

US3062157 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:06:44

All time stamps listed in this document are displayed in GMT

US3062157

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

Participant ID

US3062157

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

US3062157

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Date of Informed Consent (*dd MMM yyyy*) 7 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

US3062157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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 15:35:10

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Condition	ECZEMA, GENERALIZED
Start date (dd MMM yyyy)	UN JAN 1956
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 1956
Start Year (derived)	1956
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 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN JAN 2003
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 2003
Start Year (derived)	2003
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 15:35:10

Generated On: 09 Jun 2021 15:06:44

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN JAN 2016
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 2016
Start Year (derived)	2016
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 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN JAN 1988
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 1988
Start Year (derived)	1988
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 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 AUG 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 15:15
Height (xxx.x)	164.0 cm
Weight (xxx.x)	100.2 kg
BMI (xxx.x)	37.25461 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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 15:35:10

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:35:10

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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 15:35:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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

Visit date (dd MMM yyyy)	7 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 15:35:19

Generated On: 09 Jun 2021 15:06:44

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185229

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 15:35:19

Generated On: 09 Jun 2021 15:06:44

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 15:35:19

Generated On: 09 Jun 2021 15:06:44

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)	7 AUG 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 15:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 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 15:35:19

Generated On: 09 Jun 2021 15:06:44

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)	7 AUG 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:57
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3062157

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 16:26

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 15:35:19

Generated On: 09 Jun 2021 15:06:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 AUG 2020
Collection time (00:00-23:59)	15:42 (24 HR)
Collection date and time (derived)	7 AUG 2020 15:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:44	7 AUG 2020 15:44
Nasopharyngeal Swab 2	No		

US3062157

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

07 AUG 2020 17:02

PC Open Date & Time

07 AUG 2020 16:46

PC Close Date & Time

07 AUG 2020 19:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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 98.8 °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 AUG 2020 23:07
PC Open Date & Time	07 AUG 2020 20:11
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 13:17

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 16:16

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:12

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

12 AUG 2020 13:23

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 15:52

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

07 AUG 2020 17:03

PC Open Date & Time

07 AUG 2020 16:46

PC Close Date & Time

07 AUG 2020 19:16

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

07 AUG 2020 23:08

PC Open Date & Time

07 AUG 2020 20:11

PC Close Date & Time

08 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

08 AUG 2020 15:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

09 AUG 2020 13:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

10 AUG 2020 16:17

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

11 AUG 2020 17:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

12 AUG 2020 13:23

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

13 AUG 2020 15:52

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:04
PC Open Date & Time	07 AUG 2020 16:46
PC Close Date & Time	07 AUG 2020 19:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 23:08
PC Open Date & Time	07 AUG 2020 20:11
PC Close Date & Time	08 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

52 of 3765

EAB) (1725)

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 13:18
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 3765

EAB) (1725)

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 16:17
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 3765

EAB) (1725)

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:13
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

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EAB) (1725)

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:24
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 15:53
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3062157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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)	15:10 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:10
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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 SEP 2020
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 16:27
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3062157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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.

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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) 15:55 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:55

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

What was the frequency of the study treatment dosing? ONCE

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

US3062157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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)	15:25 (24 HR)
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Collection date and time (derived)	04 SEP 2020 15:25
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US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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	15:21	04 SEP 2020 15:21
Nasopharyngeal Swab 2	No		

US3062157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	04 SEP 2020 16:31
PC Open Date & Time	04 SEP 2020 16:15
PC Close Date & Time	04 SEP 2020 18:45

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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	05 SEP 2020 03:54
PC Open Date & Time	04 SEP 2020 19:40
PC Close Date & Time	05 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:27

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

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 SEP 2020 17:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:22

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

08 SEP 2020 17:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:43

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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 16:31

PC Open Date & Time

04 SEP 2020 16:15

PC Close Date & Time

04 SEP 2020 18:45

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

05 SEP 2020 03:55

PC Open Date & Time

04 SEP 2020 19:40

PC Close Date & Time

05 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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 18:28

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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 17:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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 15:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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 17:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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 16:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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 SEP 2020 12:44

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 16:32
PC Open Date & Time	04 SEP 2020 16:15
PC Close Date & Time	04 SEP 2020 18:45

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 03:55
PC Open Date & Time	04 SEP 2020 19:40
PC Close Date & Time	05 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:28
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:09
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 3765

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:23
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

102 of 3765

EAB) (1725)

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 17:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:06
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

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 ☒

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:45
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3062157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:10

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:19
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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.

US3062157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

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

Collection date (dd MMM yyyy)	01 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	14:33 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	01 OCT 2020 14:33
------------------------------------	-------------------

US3062157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:35:19

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 OCT 2020 10:57:48

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 OCT 2020 15:21:32
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

21 OCT 2020 21:27:51

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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	04 NOV 2020 21:25:33
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 NOV 2020 19:29:33
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 06:04:37

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

29 NOV 2020 19:51:37

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 17:19:31

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 01:59:25

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 02:00:36
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

31 DEC 2020 02:53:44

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Date and time of submission

03 JAN 2021 00:32:59

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 13:47:15

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 06:03:33

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

27 JAN 2021 10:17:44

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

31 JAN 2021 00:47:05

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

09 FEB 2021 14:44:12

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

14 FEB 2021 14:32:35

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

22 FEB 2021 00:57:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

01 MAR 2021 17:30:30

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 14:22:44

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

16 MAR 2021 13:33:57

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

22 MAR 2021 23:28:06

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

30 MAR 2021 11:53:55

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

05 APR 2021 19:54:38

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 18:40:13

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

20 APR 2021 11:47:12

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 03:50:20

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 03:14:29

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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°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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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24 FEB 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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03 MAR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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10 MAR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 <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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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°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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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°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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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="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"/>

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3062157

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:06:44

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		01 MAR 2021 17:30:52

US3062157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:00:06

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:00:06

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

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

Visit date (dd MMM yyyy)	25 FEB 2021
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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	VISIT4
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US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:10
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3062157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

13:24 (24 HR)

Collection date and time (derived)

25 FEB 2021 13:24

US3062157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:21:27

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:21:26

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062157

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:44

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"/>

US3062157

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:06:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3062157

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

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

Visit date (dd MMM yyyy)	19 JAN 2021
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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	UNBLND_DECIDE
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US3062157

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3062157

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Height	164.0 cm
Weight	102.7 kg
BMI (xxx.x)	38.18412

US3062157

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Height	164.0 cm
Weight	102.7 kg
BMI (xxx.x)	38.18412
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)	19 JAN 2021
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 13:23
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3062157

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Height	164.0 cm
Weight	102.7 kg
BMI (xxx.x)	38.18412
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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:58
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	46 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3062157

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3062157

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 14:26 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 14:26

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

US3062157

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

13:27 (24 HR)

Collection date and time (derived)

19 JAN 2021 13:27

US3062157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00 - 23:59)	13:24
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Collection Date and Time (derived)	19 JAN 2021 13:24
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US3062157

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3062157

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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

Visit date (dd MMM yyyy)	25 FEB 2021
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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	OLD29
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US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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)	25 FEB 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:10
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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)	25 FEB 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 14:43
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3062157

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3062157

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 14:12 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 14:12

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

US3062157

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062157

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:40:43

Generated On: 09 Jun 2021 15:06:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062157

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:21:26

Generated On: 09 Jun 2021 15:06:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:21:26

Generated On: 09 Jun 2021 15:06:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 APR 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 14:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062157

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:21:26

Generated On: 09 Jun 2021 15:06:44

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.

US3062157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:21:26

Generated On: 09 Jun 2021 15:06:44

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

Collection date (dd MMM yyyy)	1 APR 2021
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Collection time (00:00-23:59)	14:39 (24 HR)
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Collection date and time (derived)	1 APR 2021 14:39
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US3062157

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 21:00:06

Generated On: 09 Jun 2021 15:06:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

AEID	USA-US090-2021-MRNA-1273-P30 1000011
Adverse event	WORSENING OSTEOARTHRITIS BILATERAL KNEES
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)	27 JAN 2021
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)	27 MAR 2021
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)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	27 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	345 of 3765

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

SUBJECT NOTIFIED SITE THAT HE HAD BILATERAL KNEE REPLACEMENTS, THE FIRST ONE ON 2/11/2021, SUBJECT WAS ADMITTED FROM 2/11/2021 TO 2/13/2021. THE SECOND ONE ON 3/25/2021. SUBJECT WAS ADMITTED FROM 3/25/2021 UNTIL 3/27/2021 SUBJECT IN OFFICE AT 3/29/2021 AND SIGNED RELEASE OF RECORDS. FAXED TO SURGERY CENTER FOR RECORDS. 4/9/2021 RECEIVED MEDICAL RECORDS ON 4/8/2021, SUBJECT HAD LEFT TOTAL KNEE REPLACEMENT ON 2/11/21 AND RIGHT TOTAL KNEE REPLACEMENT ON 3/25/2021. FOLLOWING BOTH PROCEDURES SUBJECT HAD AES, AND MEDICATIONS TO HELP WITH POST OPERATIVE AES. SUBJECT HAD PAIN PRIOR TO AND FOLLOWING PROCEDURES, NSAIDS AND NARCOTIC PAIN MEDICATION ORDERED FOR PAIN CONTROL. ON 1/27/2021 SUBJECT HAD CT BILATERAL KNEES WITHOUT CONTRACT. SUBJECT WAS NOT TESTED FOR COVID WHILE ADMITTED, SUBJECT WAS ORDERED MEDICATIONS FOR THREE HEALTH HISTORY TERMS, THESE DID NOT WORSEN IN THE HOSPITAL, BUT MEDS WERE ORDERED AND ADMINISTERED. ALL NEW AND UPDATED MEDICATIONS, AES, AND PROCEDURES HAVE BEEN UPDATED IN SOURCE AND EDC.

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

POST OPERATIVE NAUSEA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

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	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)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

POST OPERATIVE
CONSTIPATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

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 (3)

Generated On: 09 Jun 2021 15:06:44

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 (4)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

MUSCLE SPASMS,
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)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

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 (4)

Generated On: 09 Jun 2021 15:06:44

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 (5)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

POST OPERATIVE 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)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

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	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 (6)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

POST OPERATIVE ITCHING

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

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	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 (7)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	11 FEB 2021
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

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	True
Concomitant Medication	False
Concomitant Procedure	False
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

POST OPERATIVE NAUSEA

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)

25 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

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	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)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	POST OPERATIVE CONSTIPATION
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)	25 MAR 2021
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)	27 MAR 2021
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 (9)

Generated On: 09 Jun 2021 15:06:44

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 (10)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	MUSCLE SPASMS, 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)	25 MAR 2021
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)	27 MAR 2021
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 (10)

Generated On: 09 Jun 2021 15:06:44

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)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	POST OPERATIVE PAIN
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)	25 MAR 2021
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)	27 MAR 2021
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

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	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 (12)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	POST OPERATIVE ITCHING
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)	25 MAR 2021
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)	27 MAR 2021
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

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	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 (13)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

OBESITY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

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	True
Concomitant Medication	False
Concomitant Procedure	False
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

AEID	
Adverse event	GASTROESOPHAGEAL REFLUX DISEASE
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)	11 FEB 2021
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 (14)

Generated On: 09 Jun 2021 15:06:44

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 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	
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 (15)

Generated On: 09 Jun 2021 15:06:44

AEID

Adverse event

OBSTRUCTIVE SLEEP APNEA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

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	True
Concomitant Medication	False
Concomitant Procedure	False
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication ELAQUIS

Prophylaxis Yes ☒
No ☐

Indication ATRIAL FIBRILLATION

Dose per administration 2.5

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 (1)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	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 (2)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication LORATADINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (3)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CLOBETASOL 0.5%

Prophylaxis Yes ☐
No ☒

Indication ECZEMA, GENERALIZED

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 2015	
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 (4)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 160

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2016	
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 120

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
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 (6)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE LEVEL

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

EVERY TWO WEEKS

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	UN FEB 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 (7)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication HYDROCODONE
7.5MG/ACETAMINOPHEN 325MG

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 2012	
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 (8)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 (8)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 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 (10)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS, BILATERAL
KNEES

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 (10)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 JUN 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 (11)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication NAIL FUNGUS, BILATERAL FEET

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	6 AUG 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 (12)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CORTISONE INJECTION

Prophylaxis Yes ☒
No ☐

Indication OSTEOARTHRITIS, BILATERAL KNEES

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 (12)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	Intraocular	<input type="radio"/>
	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	INTRARTICULAR	
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 AUG 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 (13)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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 (13)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (14)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 (15)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 ☐
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
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 (22)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (22)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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 (23)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MILK OF MAGNESIA

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 30

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 (23)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (24)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (24)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE NAUSEA

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 (25)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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 (26)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication SALINE FLUSH

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 FEB 2021	
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 (27)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

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 (27)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (28)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASMS,
GENERALIZED

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 (28)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (29)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (29)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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 (30)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

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 (30)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
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 (31)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 (31)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE ITCHING

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (36)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication PERCOCET(10/325)

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (36)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication BISACODYL SUPPOSITORY

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

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 (37)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
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 (38)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (39)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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

75ML/HR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (40)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MARCAINE 0.25%

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

Dose per administration 30

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 (40)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
		11 FEB 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MARCAINE 0.25%

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

Dose per administration 30

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 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (42)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 (43)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 15:19:18

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Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (46)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication PERCOCET(10/325)

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (47)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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 (51)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE ITCHING

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
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 (52)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE NAUSEA

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 (52)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
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 (53)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (53)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
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 (54)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 (54)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 MAR 2021		
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 (55)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
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 (56)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

Dose per administration 650

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 (56)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 MAR 2021		
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 (57)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (57)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication MILK OF MAGNESIA

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 30

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 (58)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 (59)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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 (60)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE NAUSEA

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 (60)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 MAR 2021		
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 (61)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication SALINE FLUSH

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
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 (62)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

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 (62)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
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 (63)

Data signed: (b) (4) 16 Apr 2021 15:19:18

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Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASMS,
GENERALIZED

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 (63)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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 (64)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

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 (64)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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 checked="" 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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
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 (65)

Data signed: (b) (4) 16 Apr 2021 15:19:18

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Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 (65)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 16 Apr 2021 15:19:18

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Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

Dose per administration 30

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 (66)

Data signed: (b) (4) 16 Apr 2021 15:19:18

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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)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 MAR 2021		
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"/>

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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"/>

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
BILATERAL KNEES

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

75 ML/HR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
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"/>

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Name of Medication OXYCODONE
(5/325)

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
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"/>

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:39:50

Generated On: 09 Jun 2021 15:06:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 15:19:18

Generated On: 09 Jun 2021 15:06:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	RIGHT KNEE REPLACEMENT	Medical History	
25 MAR 2021	LEFT KNEE REPLACEMENT	Adverse Event	
27 JAN 2021	CT LEFT KNEE WITHOUT CONTRAST	Adverse Event	
27 JAN 2021	CT RIGHT KNEE WITHOUT CONTRAST	Adverse Event	

US3062157

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:44

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

US3062157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:44

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 ☐

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	30/MAR/2021 11:47
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

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	07/APR/2021 09:25
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

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 15:17
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

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 20:40
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

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	13/APR/2021 21:21
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.	True

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	14/APR/2021 08:35
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

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 15:06:44

SAEID	USA-US090-2021-MRNA-1273-P301000011
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)	7
Date of submission (Pre-filled from custom function)	20/APR/2021 15:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3062157 (Prod: Alliance for Multispecialty Research, LLC)

US3062157

Form: Participant Creation

Generated On: 09 Jun 2021 15:06:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:09:35
User entered 'US3062157'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:19

US3062157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:19:11
User entered 'Yes (Y)'	Riley King (b) (4)	07 Aug 2020 21:31:11
	(b) (4)	

US3062157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:19:11
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:20

US3062157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:19:11
User entered 'Clinic (Clinic)'	Riley King (b) (4)	07 Aug 2020 21:31:11
	(b) (4)	

US3062157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'SCRN'	System	07 Aug 2020 21:31:11

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:21

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 04:43:31
Query 'Per CDM: Please complete this form.' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	20 Aug 2020 18:59:22
	(b) (4)	
User entered '65'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 14:47:05

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User entered 'YEARS'	System	20 Aug 2020 18:59:11

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User entered '65'	System	07 Aug 2020 21:31:21

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered 'Male (M)'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered 'I'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered empty.	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:20:28
User entered '0'	Janna Martinez (b) (4)	20 Aug 2020 18:59:11
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered '7 Aug 2020'	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User entered 'Aug 2020'	System	07 Aug 2020 21:31:21

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User entered '2020'	System	07 Aug 2020 21:31:21

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered 'Amendment 1 (1)'	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered 'Yes (Y)'	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered empty.	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered empty.	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:31:21
	(b) (4)	

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:20

US3062157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User entered 'I'	System	07 Aug 2020 21:31:25

US3062157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:17
User entered 'Yes (Y)'	Riley King (b) (4)	07 Aug 2020 21:31:25
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:06:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:22:38
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 20:38:08
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 20:41:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 20:41:41
Data point term sent to Coder	System	09 Aug 2020 20:41:14
User entered 'seasonal allergies'	Sherry Henning (b) (4)	09 Aug 2020 20:40:58

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:13:04
DataPoint Un-verified.	marissa Mueller (b) (4)	09 Sep 2020 23:42:20
	(b) (4)	
User entered 'UN Jan 2010' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Sep 2020 23:42:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2012'	Sherry Henning (b) (4)	09 Aug 2020 20:40:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:40:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 20:40:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 20:40:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:40:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2010'	System	09 Sep 2020 23:42:20
User entered 'Jan 2012'	System	09 Aug 2020 20:40:58

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2010'	System	09 Sep 2020 23:42:20
User entered '2012'	System	09 Aug 2020 20:40:58

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:40:58

US3062157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:40:58

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 09:51:07
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 09:51:07
Data point term sent to Coder	System	09 Aug 2020 20:58:23
User entered 'eczema, generalized'	Sherry Henning (b) (4)	09 Aug 2020 20:57:37

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 1956'	Sherry Henning (b) (4)	09 Aug 2020 20:57:37
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:57:37
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 20:57:37
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 20:57:37
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:57:37
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 1956'	System	09 Aug 2020 20:57:37

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '1956'	System	09 Aug 2020 20:57:37

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:57:37

US3062157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:57:37

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Fungal infection of nail - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 09:11:22
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 09:11:22
Data point term sent to Coder	System	09 Aug 2020 21:00:24
User entered 'Nail fungus, bilateral feet'	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2010'	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 20:59:55
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2010'	System	09 Aug 2020 20:59:55

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2010'	System	09 Aug 2020 20:59:55

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:59:55

US3062157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 20:59:55

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:00:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:00:39
Data point term sent to Coder	System	09 Aug 2020 21:00:24
User entered 'atrial fibrillation'	Sherry Henning (b) (4)	09 Aug 2020 21:00:22

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2003'	Sherry Henning (b) (4)	09 Aug 2020 21:00:22
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:00:22
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:00:22
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:00:22
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:00:22
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2003'	System	09 Aug 2020 21:00:22

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2003'	System	09 Aug 2020 21:00:22

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:00:22

US3062157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:00:22

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:06:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:06:26
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Aug 2020 21:05:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Aug 2020 21:05:58
User entered 'hypercholesterolemia' reason for change: Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 21:05:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Aug 2020 21:00:56
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	09 Aug 2020 21:05:58
User entered 'un Jan 2016' reason for change: Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 21:05:58
	(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	09 Aug 2020 21:00:56
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Aug 2020 21:05:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Aug 2020 21:05:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 21:05:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Aug 2020 21:00:56
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:00:56
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2016'	System	09 Aug 2020 21:05:58
User entered empty.	System	09 Aug 2020 21:00:56

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2016'	System	09 Aug 2020 21:05:58
User entered empty.	System	09 Aug 2020 21:00:56

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:00:56

US3062157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:00:56

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:43
Data point term sent to Coder	System	09 Aug 2020 21:07:28
User entered 'low testosterone level'	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2018'	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:06:33
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2018'	System	09 Aug 2020 21:06:33

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2018'	System	09 Aug 2020 21:06:33

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:06:33

US3062157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:06:33

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:43
Data point term sent to Coder	System	09 Aug 2020 21:07:28
User entered 'chronic back pain'	Sherry Henning (b) (4)	09 Aug 2020 21:06:58

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 1988'	Sherry Henning (b) (4)	09 Aug 2020 21:06:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:06:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:06:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:06:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:06:58
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 1988'	System	09 Aug 2020 21:06:58

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '1988'	System	09 Aug 2020 21:06:58

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:06:58

US3062157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:06:58

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:08:42
Data point term sent to Coder	System	09 Aug 2020 21:07:27
User entered 'osteoarthritis, bilateral knees'	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2018'	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:07:26
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2018'	System	09 Aug 2020 21:07:26

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2018'	System	09 Aug 2020 21:07:26

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:07:26

US3062157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:07:26

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:09:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 21:09:43
Data point term sent to Coder	System	09 Aug 2020 21:08:29
User entered 'depression'	Sherry Henning (b) (4)	09 Aug 2020 21:07:45

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'un Jan 2014'	Sherry Henning (b) (4)	09 Aug 2020 21:07:45
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:07:45
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:07:45
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:07:45
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:23:06
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:07:45
	(b) (4)	

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'Jan 2014'	System	09 Aug 2020 21:07:45

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '2014'	System	09 Aug 2020 21:07:45

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:07:45

US3062157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered empty.	System	09 Aug 2020 21:07:45

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered '15:15'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered '7 Aug 2020 15:15'	System	09 Aug 2020 21:11:01

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered '164.0' cm	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	
DataPoint set to visible.	System	07 Aug 2020 21:31:25

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered '100.2' kg	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	
DataPoint set to visible.	System	07 Aug 2020 21:31:25

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
Amendment Manager: User entered '37.25461'	System	16 Sep 2020 23:48:18
User entered '37.3'	System	09 Aug 2020 21:11:01
DataPoint set to visible.	System	07 Aug 2020 21:31:25

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'kg/m2'	System	09 Aug 2020 21:11:01
DataPoint set to visible.	System	07 Aug 2020 21:31:25

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
User entered '97.5' F	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
User entered '53'	(b) (4)	
	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'bpm'	System	09 Aug 2020 21:11:01

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
User entered '14'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'breaths/min'	System	09 Aug 2020 21:11:01

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
User entered '134'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'mmHg'	System	09 Aug 2020 21:11:01

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:05
User entered '96'	Sherry Henning (b) (4)	09 Aug 2020 21:11:01
	(b) (4)	

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User entered 'mmHg'	System	09 Aug 2020 21:11:01

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30

US3062157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30

US3062157

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 21:18:16
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:11:17
	(b) (4)	

US3062157

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:25:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.'	(b) (4), (b) (6)	06 Sep 2020 13:29:57
canceled (Site from System).		
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 21:00:57
User entered '07 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 21:18:16
	(b) (4)	
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:11:17
	(b) (4)	

US3062157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

US3062157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

US3062157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

US3062157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

US3062157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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[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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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Folder: Screening

Form: Risk of Exposure

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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Folder: Screening

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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Folder: Screening

Form: Risk of Exposure

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[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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered 'I'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(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 11:19:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:33
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:12:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:58
User entered 'Yes (Y)'	Riley King (b) (4)	07 Aug 2020 21:31:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:58
User entered '7 Aug 2020'	Riley King (b) (4)	07 Aug 2020 21:31:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[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 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:30:58
User entered 'Clinic (Clinic)'	Riley King (b) (4)	07 Aug 2020 21:31:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'VISIT1'	System	07 Aug 2020 21:31:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:04:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:00:53
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:00:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 21:04:08
User entered '185229' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:04:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:04:08

US3062157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

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 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:32:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:32:02

US3062157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:32:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:32:02
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:40:55
User entered 'No (N)'	Riley King (b) (4)	07 Aug 2020 21:32:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '164.0' cm	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '100.2' kg	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '164.0' cm	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '100.2' kg	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '15:15'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered '7 Aug 2020 15:15'	System	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '97.5' F	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '53'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'bpm'	System	09 Aug 2020 21:16:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '14'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'breaths/min'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '134'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'mmHg'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '96'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'mmHg'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '164.0' cm	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:15
User entered '100.2' kg	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
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 07:38:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as entered' (Site from System).	Sherry Henning (b) (4)	09 Aug 2020 21:16:34
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).		09 Aug 2020 21:16:14
User entered '16:57'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered '7 Aug 2020 16:57'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '98.5' F	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '57'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'bpm'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '14'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'breaths/min'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '116'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'mmHg'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:43:41
User entered '84'	Sherry Henning (b) (4)	09 Aug 2020 21:16:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'mmHg'	System	09 Aug 2020 21:16:14

US3062157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:55:53
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:34
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:18:44

US3062157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:55:53
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:52:34
	(b) (4)	
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:18:44
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered 'Yes (Y)'	Riley King (b) (4)	07 Aug 2020 21:32:17
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered empty.	Riley King (b) (4)	07 Aug 2020 21:32:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered empty.	Riley King (b) (4)	07 Aug 2020 21:32:17

US3062157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 21:32:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered '7 Aug 2020'	Riley King (b) (4)	07 Aug 2020 21:32:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered '16:26'	Riley King (b) (4)	07 Aug 2020 21:32:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered '7 Aug 2020 16:26'	System	07 Aug 2020 21:32:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered 'Left Arm (LEFT ARM)'	Riley King (b) (4)	07 Aug 2020 21:32:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:56:19
User entered 'ONCE'	System	07 Aug 2020 21:32:17

US3062157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 21:32:17

US3062157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:13:43
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:23:49

US3062157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:13:43
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:23:49
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:13:43
User entered '15:42'	Sherry Henning (b) (4)	09 Aug 2020 21:23:49
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered '7 Aug 2020 15:42'	System	09 Aug 2020 21:23:49

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:58
User entered '7 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:58
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:49:22
User closed query 'Per source this sample was collected at 15:44. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 19:49:21
Query 'Per source this sample was collected at 15:44. Please verify and update if needed.' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	06 Oct 2020 18:52:01
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	06 Oct 2020 18:51:56
	(b) (4)	
User entered '15:44' reason for change: Data Entry Error	marissa Mueller (b) (4)	06 Oct 2020 18:51:56
	(b) (4)	
User opened query 'Per source this sample was collected at 15:44. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:58
User entered '15:42'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered '7 Aug 2020 15:44'	System	06 Oct 2020 18:51:56
User entered '7 Aug 2020 15:42'	System	09 Aug 2020 21:24:14

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:58
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:24:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:58
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:24:14

US3062157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered empty.	System	09 Aug 2020 21:24:14

US3062157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:27:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:24:40
	(b) (4)	

US3062157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'I'	System	09 Aug 2020 21:24:40

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:02:07', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9efe6faa-4665-46d8-89ef-19307e444c66'	System	07 Aug 2020 22:02:51
User entered 'Yes (Y)'	System	07 Aug 2020 22:02:51

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:02:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9efe6faa-4665-46d8-89ef-19307e444c66'	System	07 Aug 2020 22:02:51
User entered '98.5'	System	07 Aug 2020 22:02:51

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:02:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9efe6faa-4665-46d8-89ef-19307e444c66'	System	07 Aug 2020 22:02:51
User entered 'No (N)'	System	07 Aug 2020 22:02:51

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:02:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9efe6faa-4665-46d8-89ef-19307e444c66'	System	07 Aug 2020 22:02:51
User entered '07 Aug 2020 17:02'	System	07 Aug 2020 22:02:51

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 16:46'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 19:16'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:06:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4e95ed83-f0a8-4d1f-a7c6-5af30487f8f2'	System	08 Aug 2020 04:07:35
User entered 'Yes (Y)'	System	08 Aug 2020 04:07:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:07:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4e95ed83-f0a8-4d1f-a7c6-5af30487f8f2'	System	08 Aug 2020 04:07:35
User entered '98.8'	System	08 Aug 2020 04:07:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:07:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4e95ed83-f0a8-4d1f-a7c6-5af30487f8f2'	System	08 Aug 2020 04:07:35
User entered 'No (N)'	System	08 Aug 2020 04:07:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:07:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4e95ed83-f0a8-4d1f-a7c6-5af30487f8f2'	System	08 Aug 2020 04:07:35
User entered '07 Aug 2020 23:07'	System	08 Aug 2020 04:07:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 20:11'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 2'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:02:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'dd4bb6ae-9e76-4668-bc06-ad012d563631'	System	08 Aug 2020 20:03:05
User entered 'Yes (Y)'	System	08 Aug 2020 20:03:05

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:02:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'dd4bb6ae-9e76-4668-bc06-ad012d563631'	System	08 Aug 2020 20:03:05
User entered '98.6'	System	08 Aug 2020 20:03:05

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:02:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'dd4bb6ae-9e76-4668-bc06-ad012d563631'	System	08 Aug 2020 20:03:05
User entered 'No (N)'	System	08 Aug 2020 20:03:05

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'dd4bb6ae-9e76-4668-bc06-ad012d563631'	System	08 Aug 2020 20:03:05
User entered '08 Aug 2020 15:03'	System	08 Aug 2020 20:03:05

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 3'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:17:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1fb5409a-075b-4e6d-8c9e-cb328a425a95'	System	09 Aug 2020 18:17:57
User entered 'Yes (Y)'	System	09 Aug 2020 18:17:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:17:47', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1fb5409a-075b-4e6d-8c9e-cb328a425a95'	System	09 Aug 2020 18:17:57
User entered '98.5'	System	09 Aug 2020 18:17:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:17:51', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1fb5409a-075b-4e6d-8c9e-cb328a425a95'	System	09 Aug 2020 18:17:57
User entered 'No (N)'	System	09 Aug 2020 18:17:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:17:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1fb5409a-075b-4e6d-8c9e-cb328a425a95'	System	09 Aug 2020 18:17:57
User entered '09 Aug 2020 13:17'	System	09 Aug 2020 18:17:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 4'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:24', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '55317c04-b9d1-452a-9d12-3b4df08f33bb'	System	10 Aug 2020 21:16:42
User entered 'Yes (Y)'	System	10 Aug 2020 21:16:42

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '55317c04-b9d1-452a-9d12-3b4df08f33bb'	System	10 Aug 2020 21:16:42
User entered '98.4'	System	10 Aug 2020 21:16:42

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '55317c04-b9d1-452a-9d12-3b4df08f33bb'	System	10 Aug 2020 21:16:42
User entered 'No (N)'	System	10 Aug 2020 21:16:42

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '55317c04-b9d1-452a-9d12-3b4df08f33bb'	System	10 Aug 2020 21:16:42
User entered '10 Aug 2020 16:16'	System	10 Aug 2020 21:16:42

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 5'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:12:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2141a9c5-5fe8-482d-ad28-b4e4b4cd9982'	System	11 Aug 2020 22:12:57
User entered 'Yes (Y)'	System	11 Aug 2020 22:12:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:12:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2141a9c5-5fe8-482d-ad28-b4e4b4cd9982'	System	11 Aug 2020 22:12:57
User entered '98.5'	System	11 Aug 2020 22:12:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:12:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2141a9c5-5fe8-482d-ad28-b4e4b4cd9982'	System	11 Aug 2020 22:12:57
User entered 'No (N)'	System	11 Aug 2020 22:12:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:12:58', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2141a9c5-5fe8-482d-ad28-b4e4b4cd9982'	System	11 Aug 2020 22:12:57
User entered '11 Aug 2020 17:12'	System	11 Aug 2020 22:12:57

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 6'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:22:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '457f4c7f-ceb1-4730-a76b-aab59b1b521e'	System	12 Aug 2020 18:23:20
User entered 'Yes (Y)'	System	12 Aug 2020 18:23:20

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '457f4c7f-ceb1-4730-a76b-aab59b1b521e'	System	12 Aug 2020 18:23:20
User entered '97.9'	System	12 Aug 2020 18:23:20

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:16', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '457f4c7f-ceb1-4730-a76b-aab59b1b521e'	System	12 Aug 2020 18:23:20
User entered 'No (N)'	System	12 Aug 2020 18:23:20

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '457f4c7f-ceb1-4730-a76b-aab59b1b521e'	System	12 Aug 2020 18:23:20
User entered '12 Aug 2020 13:23'	System	12 Aug 2020 18:23:20

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 7'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:10', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '3f3061fd-d033-4ba6-9c92-c98a4ab0bd82'	System	13 Aug 2020 20:52:35
User entered 'Yes (Y)'	System	13 Aug 2020 20:52:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '3f3061fd-d033-4ba6-9c92-c98a4ab0bd82'	System	13 Aug 2020 20:52:35
User entered '98.7'	System	13 Aug 2020 20:52:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '3f3061fd-d033-4ba6-9c92-c98a4ab0bd82'	System	13 Aug 2020 20:52:35
User entered 'No (N)'	System	13 Aug 2020 20:52:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '3f3061fd-d033-4ba6-9c92-c98a4ab0bd82'	System	13 Aug 2020 20:52:35
User entered '13 Aug 2020 15:52'	System	13 Aug 2020 20:52:35

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:02:59', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0c879016-de42-41f7-a454-f29412c5f752'	System	07 Aug 2020 22:03:34
User entered 'None (1)'	System	07 Aug 2020 22:03:34

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0c879016-de42-41f7-a454-f29412c5f752'	System	07 Aug 2020 22:03:34
User entered 'No (N)'	System	07 Aug 2020 22:03:34

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:07', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0c879016-de42-41f7-a454-f29412c5f752'	System	07 Aug 2020 22:03:34
User entered 'No (N)'	System	07 Aug 2020 22:03:34

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0c879016-de42-41f7-a454-f29412c5f752'	System	07 Aug 2020 22:03:34
User entered 'None (1)'	System	07 Aug 2020 22:03:34

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0c879016-de42-41f7-a454-f29412c5f752'	System	07 Aug 2020 22:03:34
User entered '07 Aug 2020 17:03'	System	07 Aug 2020 22:03:34

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 16:46'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 19:16'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:07:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'aaa14f9b-6bd3-4ee7-8712-ce3a7d8036c9'	System	08 Aug 2020 04:08:28
User entered 'None (1)'	System	08 Aug 2020 04:08:28

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'aaa14f9b-6bd3-4ee7-8712-ce3a7d8036c9'	System	08 Aug 2020 04:08:28
User entered 'No (N)'	System	08 Aug 2020 04:08:28

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'aaa14f9b-6bd3-4ee7-8712-ce3a7d8036c9'	System	08 Aug 2020 04:08:28
User entered 'No (N)'	System	08 Aug 2020 04:08:28

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:20', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'aaa14f9b-6bd3-4ee7-8712-ce3a7d8036c9'	System	08 Aug 2020 04:08:28
User entered 'None (1)'	System	08 Aug 2020 04:08:28

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'aaa14f9b-6bd3-4ee7-8712-ce3a7d8036c9'	System	08 Aug 2020 04:08:28
User entered '07 Aug 2020 23:08'	System	08 Aug 2020 04:08:28

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 20:11'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 2'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:13', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '5fa013d6-493a-48f5-afab-2c3b43dc189b'	System	08 Aug 2020 20:03:38
User entered 'None (1)'	System	08 Aug 2020 20:03:38

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '5fa013d6-493a-48f5-afab-2c3b43dc189b'	System	08 Aug 2020 20:03:38
User entered 'No (N)'	System	08 Aug 2020 20:03:38

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '5fa013d6-493a-48f5-afab-2c3b43dc189b'	System	08 Aug 2020 20:03:38
User entered 'No (N)'	System	08 Aug 2020 20:03:38

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '5fa013d6-493a-48f5-afab-2c3b43dc189b'	System	08 Aug 2020 20:03:38
User entered 'None (1)'	System	08 Aug 2020 20:03:38

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '5fa013d6-493a-48f5-afab-2c3b43dc189b'	System	08 Aug 2020 20:03:38
User entered '08 Aug 2020 15:03'	System	08 Aug 2020 20:03:38

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 3'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '8ae902b1-af3b-4a44-aaa2-5985a708cf51'	System	09 Aug 2020 18:18:31
User entered 'None (1)'	System	09 Aug 2020 18:18:31

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:07', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '8ae902b1-af3b-4a44-aaa2-5985a708cf51'	System	09 Aug 2020 18:18:31
User entered 'No (N)'	System	09 Aug 2020 18:18:31

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '8ae902b1-af3b-4a44-aaa2-5985a708cf51'	System	09 Aug 2020 18:18:31
User entered 'No (N)'	System	09 Aug 2020 18:18:31

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '8ae902b1-af3b-4a44-aaa2-5985a708cf51'	System	09 Aug 2020 18:18:31
User entered 'None (1)'	System	09 Aug 2020 18:18:31

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '8ae902b1-af3b-4a44-aaa2-5985a708cf51'	System	09 Aug 2020 18:18:31
User entered '09 Aug 2020 13:18'	System	09 Aug 2020 18:18:31

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 4'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '417cd606-b3a5-46d9-b182-45e5d4701c78'	System	10 Aug 2020 21:17:08
User entered 'None (1)'	System	10 Aug 2020 21:17:08

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:53', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '417cd606-b3a5-46d9-b182-45e5d4701c78'	System	10 Aug 2020 21:17:08
User entered 'No (N)'	System	10 Aug 2020 21:17:08

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:16:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '417cd606-b3a5-46d9-b182-45e5d4701c78'	System	10 Aug 2020 21:17:08
User entered 'No (N)'	System	10 Aug 2020 21:17:08

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '417cd606-b3a5-46d9-b182-45e5d4701c78'	System	10 Aug 2020 21:17:08
User entered 'None (1)'	System	10 Aug 2020 21:17:08

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '417cd606-b3a5-46d9-b182-45e5d4701c78'	System	10 Aug 2020 21:17:08
User entered '10 Aug 2020 16:17'	System	10 Aug 2020 21:17:08

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 5'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf000a9f-e451-400a-b4f8-864e52194bf2'	System	11 Aug 2020 22:13:24
User entered 'None (1)'	System	11 Aug 2020 22:13:24

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:07', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf000a9f-e451-400a-b4f8-864e52194bf2'	System	11 Aug 2020 22:13:24
User entered 'No (N)'	System	11 Aug 2020 22:13:24

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:10', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf000a9f-e451-400a-b4f8-864e52194bf2'	System	11 Aug 2020 22:13:24
User entered 'No (N)'	System	11 Aug 2020 22:13:24

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf000a9f-e451-400a-b4f8-864e52194bf2'	System	11 Aug 2020 22:13:24
User entered 'None (1)'	System	11 Aug 2020 22:13:24

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:24', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf000a9f-e451-400a-b4f8-864e52194bf2'	System	11 Aug 2020 22:13:24
User entered '11 Aug 2020 17:13'	System	11 Aug 2020 22:13:24

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 6'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '85c8302e-3e90-4414-943c-02b78b4c87ec'	System	12 Aug 2020 18:23:39
User entered 'None (1)'	System	12 Aug 2020 18:23:39

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '85c8302e-3e90-4414-943c-02b78b4c87ec'	System	12 Aug 2020 18:23:39
User entered 'No (N)'	System	12 Aug 2020 18:23:39

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '85c8302e-3e90-4414-943c-02b78b4c87ec'	System	12 Aug 2020 18:23:39
User entered 'No (N)'	System	12 Aug 2020 18:23:39

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:34', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '85c8302e-3e90-4414-943c-02b78b4c87ec'	System	12 Aug 2020 18:23:39
User entered 'None (1)'	System	12 Aug 2020 18:23:39

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '85c8302e-3e90-4414-943c-02b78b4c87ec'	System	12 Aug 2020 18:23:39
User entered '12 Aug 2020 13:23'	System	12 Aug 2020 18:23:39

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 7'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '299a2eb8-be19-4c80-9119-6bf1757d54ad'	System	13 Aug 2020 20:52:56
User entered 'None (1)'	System	13 Aug 2020 20:52:56

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '299a2eb8-be19-4c80-9119-6bf1757d54ad'	System	13 Aug 2020 20:52:56
User entered 'No (N)'	System	13 Aug 2020 20:52:56

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '299a2eb8-be19-4c80-9119-6bf1757d54ad'	System	13 Aug 2020 20:52:56
User entered 'No (N)'	System	13 Aug 2020 20:52:56

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '299a2eb8-be19-4c80-9119-6bf1757d54ad'	System	13 Aug 2020 20:52:56
User entered 'None (1)'	System	13 Aug 2020 20:52:56

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:52:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '299a2eb8-be19-4c80-9119-6bf1757d54ad'	System	13 Aug 2020 20:52:56
User entered '13 Aug 2020 15:52'	System	13 Aug 2020 20:52:56

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:38', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'None (0)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:03:59', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered 'No (N)'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T17:04:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '842df8dc-643c-4fc8-a8ba-69947d6631db'	System	07 Aug 2020 22:04:04
User entered '07 Aug 2020 17:04'	System	07 Aug 2020 22:04:04

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 16:46'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 19:16'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:39', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:45', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'None (0)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered 'No (N)'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-07T23:08:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '60ff3570-2b1d-4146-bbf0-80aabd7761d5'	System	08 Aug 2020 04:08:59
User entered '07 Aug 2020 23:08'	System	08 Aug 2020 04:08:59

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Aug 2020 20:11'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 2'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:45', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:03:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:04:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:04:04', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'None (0)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:04:08', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered 'No (N)'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-08T15:04:16', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a5841b7f-35bd-4660-bafd-05736ed8731e'	System	08 Aug 2020 20:04:16
User entered '08 Aug 2020 15:04'	System	08 Aug 2020 20:04:16

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 3'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:43', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'None (0)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered 'No (N)'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-09T13:18:59', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '064b1e9a-b7a3-49a4-bb17-079bcb01485b'	System	09 Aug 2020 18:19:00
User entered '09 Aug 2020 13:18'	System	09 Aug 2020 18:19:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 4'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'None (0)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered 'No (N)'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-10T16:17:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '7f5b33da-2229-4c33-9ec1-46e1bc2f9369'	System	10 Aug 2020 21:17:43
User entered '10 Aug 2020 16:17'	System	10 Aug 2020 21:17:43

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 5'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:38', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:41', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'None (0)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered 'No (N)'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-11T17:13:50', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36fe98e4-e299-4398-8074-d5f92efd1bec'	System	11 Aug 2020 22:13:50
User entered '11 Aug 2020 17:13'	System	11 Aug 2020 22:13:50

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 6'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:51', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'None (0)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:23:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered 'No (N)'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-12T13:24:00', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e505c459-7082-4185-b22a-532cf9c998b0'	System	12 Aug 2020 18:24:00
User entered '12 Aug 2020 13:24'	System	12 Aug 2020 18:24:00

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 7'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:08', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:14', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'None (0)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:20', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered 'No (N)'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-08-13T15:53:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '49eafecc-80f5-4c63-8673-ec7e62d73a02'	System	13 Aug 2020 20:53:21
User entered '13 Aug 2020 15:53'	System	13 Aug 2020 20:53:21

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 21:32:17

US3062157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:06
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:49:24
	(b) (4)	

US3062157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:06
User entered '17 Aug 2020'	Janna Martinez (b) (4)	19 Aug 2020 19:49:24
	(b) (4)	

US3062157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:06
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	19 Aug 2020 19:49:24
	(b) (4)	

US3062157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:06
User entered empty.	Janna Martinez (b) (4)	19 Aug 2020 19:49:24
	(b) (4)	

US3062157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:26
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:49:08
	(b) (4)	

US3062157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'I'	System	19 Aug 2020 19:49:08

US3062157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:16
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 17:04:50
	(b) (4)	

US3062157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:16
User entered '22 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 17:04:50
	(b) (4)	

US3062157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:16
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	26 Aug 2020 17:04:50
	(b) (4)	

US3062157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:16
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 17:04:50
	(b) (4)	

US3062157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:20
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 17:04:42
	(b) (4)	

US3062157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:04:01
User entered 'I'	System	26 Aug 2020 17:04:42

US3062157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:43
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 21:00:26
	(b) (4)	

US3062157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:43
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Sep 2020 21:00:39
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	04 Sep 2020 21:00:39
User entered '28 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	04 Sep 2020 21:00:39
	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Sep 2020 21:00:26
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 21:00:26
	(b) (4)	

US3062157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:43
User entered 'Contact Made (CONTACT MADE)'	Brianna Burton (b) (4)	04 Sep 2020 21:00:26
	(b) (4)	

US3062157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:43
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 21:00:26
	(b) (4)	

US3062157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:28:49
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 21:00:46
	(b) (4)	

US3062157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:47
User entered 'I'	System	04 Sep 2020 21:00:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:17:35
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 21:00:57
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:17:35
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 21:00:57
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:17:35
User entered 'Clinic (Clinic)'	Brianna Burton (b) (4)	04 Sep 2020 21:00:57
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'VISIT2'	System	04 Sep 2020 21:00:57

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '15:10'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '04 Sep 2020 15:10'	System	04 Sep 2020 21:42:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '99.1' F	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '57'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'bpm'	System	04 Sep 2020 21:42:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '14'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'breaths/min'	System	04 Sep 2020 21:42:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '116'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	04 Sep 2020 21:42:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '84'	Janna Martinez (b) (4)	04 Sep 2020 21:42:46
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	04 Sep 2020 21:42:46

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '16:27'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '04 Sep 2020 16:27'	System	04 Sep 2020 21:43:39

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 21:43:50
User entered '98.6' F reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 21:43:50
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 21:43:39
User entered '98..6' (non-conformant).	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '50'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'bpm'	System	04 Sep 2020 21:43:39

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '16'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'breaths/min'	System	04 Sep 2020 21:43:39

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '116'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	04 Sep 2020 21:43:39

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:04
User entered '84'	Janna Martinez (b) (4)	04 Sep 2020 21:43:39
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	04 Sep 2020 21:43:39

US3062157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:24
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:04
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:20:24
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:44:04
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:01:18

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered '15:55'	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '4 Sep 2020 15:55'	System	04 Sep 2020 21:01:18

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered 'Left Arm (LEFT ARM)'	Brianna Burton (b) (4)	04 Sep 2020 21:01:18
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:18
User entered 'ONCE'	System	04 Sep 2020 21:01:18

US3062157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:01:18

US3062157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:18:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:28
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:18:57
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:44:28
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:18:57
User entered '15:25'	Janna Martinez (b) (4)	04 Sep 2020 21:44:28
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '04 Sep 2020 15:25'	System	04 Sep 2020 21:44:28

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:01
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:01
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:01
User entered '15:21'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '04 Sep 2020 15:21'	System	04 Sep 2020 21:44:41

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:01
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:01
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 21:44:41
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered empty.	System	04 Sep 2020 21:44:41

US3062157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:19:37
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:44:55
	(b) (4)	

US3062157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	04 Sep 2020 21:44:55

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:30:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bbcbab0c-ccd9-46bb-9f0b-d2fb076bbc38'	System	04 Sep 2020 21:31:17
User entered 'Yes (Y)'	System	04 Sep 2020 21:31:17

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bbcbab0c-ccd9-46bb-9f0b-d2fb076bbc38'	System	04 Sep 2020 21:31:17
User entered '98.6'	System	04 Sep 2020 21:31:17

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bbcbab0c-ccd9-46bb-9f0b-d2fb076bbc38'	System	04 Sep 2020 21:31:17
User entered 'No (N)'	System	04 Sep 2020 21:31:17

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bbcbab0c-ccd9-46bb-9f0b-d2fb076bbc38'	System	04 Sep 2020 21:31:17
User entered '04 Sep 2020 16:31'	System	04 Sep 2020 21:31:17

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 16:15'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 18:45'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9cbaede8-2bd2-4554-aa20-fa9db82a1ee3'	System	05 Sep 2020 08:54:16
User entered 'Yes (Y)'	System	05 Sep 2020 08:54:16

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9cbaede8-2bd2-4554-aa20-fa9db82a1ee3'	System	05 Sep 2020 08:54:16
User entered '98.4'	System	05 Sep 2020 08:54:16

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:13', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9cbaede8-2bd2-4554-aa20-fa9db82a1ee3'	System	05 Sep 2020 08:54:16
User entered 'No (N)'	System	05 Sep 2020 08:54:16

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9cbaede8-2bd2-4554-aa20-fa9db82a1ee3'	System	05 Sep 2020 08:54:16
User entered '05 Sep 2020 03:54'	System	05 Sep 2020 08:54:16

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 2'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b8d5ffdc-282d-4680-897e-d81154c16fb9'	System	05 Sep 2020 23:27:37
User entered 'Yes (Y)'	System	05 Sep 2020 23:27:37

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b8d5ffdc-282d-4680-897e-d81154c16fb9'	System	05 Sep 2020 23:27:37
User entered '98.6'	System	05 Sep 2020 23:27:37

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b8d5ffdc-282d-4680-897e-d81154c16fb9'	System	05 Sep 2020 23:27:37
User entered 'No (N)'	System	05 Sep 2020 23:27:37

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b8d5ffdc-282d-4680-897e-d81154c16fb9'	System	05 Sep 2020 23:27:37
User entered '05 Sep 2020 18:27'	System	05 Sep 2020 23:27:37

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 3'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '872ebb4e-385e-4243-a219-6cc625dd1331'	System	06 Sep 2020 22:07:39
User entered 'Yes (Y)'	System	06 Sep 2020 22:07:39

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '872ebb4e-385e-4243-a219-6cc625dd1331'	System	06 Sep 2020 22:07:39
User entered '98.3'	System	06 Sep 2020 22:07:39

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '872ebb4e-385e-4243-a219-6cc625dd1331'	System	06 Sep 2020 22:07:39
User entered 'No (N)'	System	06 Sep 2020 22:07:39

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '872ebb4e-385e-4243-a219-6cc625dd1331'	System	06 Sep 2020 22:07:39
User entered '06 Sep 2020 17:07'	System	06 Sep 2020 22:07:39

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 4'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4b45b0fc-6e61-482f-9b66-1ff0511b6a7a'	System	07 Sep 2020 20:22:46
User entered 'Yes (Y)'	System	07 Sep 2020 20:22:46

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4b45b0fc-6e61-482f-9b66-1ff0511b6a7a'	System	07 Sep 2020 20:22:46
User entered '98.6'	System	07 Sep 2020 20:22:46

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4b45b0fc-6e61-482f-9b66-1ff0511b6a7a'	System	07 Sep 2020 20:22:46
User entered 'No (N)'	System	07 Sep 2020 20:22:46

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4b45b0fc-6e61-482f-9b66-1ff0511b6a7a'	System	07 Sep 2020 20:22:46
User entered '07 Sep 2020 15:22'	System	07 Sep 2020 20:22:46

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 5'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:28:58', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9b8cab09-5dec-47fc-8f31-2bab235467a0'	System	08 Sep 2020 22:29:20
User entered 'Yes (Y)'	System	08 Sep 2020 22:29:20

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9b8cab09-5dec-47fc-8f31-2bab235467a0'	System	08 Sep 2020 22:29:20
User entered '98.4'	System	08 Sep 2020 22:29:20

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9b8cab09-5dec-47fc-8f31-2bab235467a0'	System	08 Sep 2020 22:29:20
User entered 'No (N)'	System	08 Sep 2020 22:29:20

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9b8cab09-5dec-47fc-8f31-2bab235467a0'	System	08 Sep 2020 22:29:20
User entered '08 Sep 2020 17:29'	System	08 Sep 2020 22:29:20

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 6'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1a726e5e-bfc7-4a84-b2ae-355ec0154db6'	System	09 Sep 2020 21:05:26
User entered 'Yes (Y)'	System	09 Sep 2020 21:05:26

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:14', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1a726e5e-bfc7-4a84-b2ae-355ec0154db6'	System	09 Sep 2020 21:05:26
User entered '98.4'	System	09 Sep 2020 21:05:26

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1a726e5e-bfc7-4a84-b2ae-355ec0154db6'	System	09 Sep 2020 21:05:26
User entered 'No (N)'	System	09 Sep 2020 21:05:26

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1a726e5e-bfc7-4a84-b2ae-355ec0154db6'	System	09 Sep 2020 21:05:26
User entered '09 Sep 2020 16:05'	System	09 Sep 2020 21:05:26

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 7'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:43:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'fdbb0a30-161f-4a5d-a2ac-04e4d6f31887'	System	10 Sep 2020 17:43:59
User entered 'Yes (Y)'	System	10 Sep 2020 17:43:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:43:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'fdbb0a30-161f-4a5d-a2ac-04e4d6f31887'	System	10 Sep 2020 17:43:59
User entered '98.5'	System	10 Sep 2020 17:43:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:43:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'fdbb0a30-161f-4a5d-a2ac-04e4d6f31887'	System	10 Sep 2020 17:43:59
User entered 'No (N)'	System	10 Sep 2020 17:43:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:43:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'fdbb0a30-161f-4a5d-a2ac-04e4d6f31887'	System	10 Sep 2020 17:43:59
User entered '10 Sep 2020 12:43'	System	10 Sep 2020 17:43:59

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'af20d870-fb8e-488a-a94a-5035fb80f4e0'	System	04 Sep 2020 21:31:40
User entered 'None (1)'	System	04 Sep 2020 21:31:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'af20d870-fb8e-488a-a94a-5035fb80f4e0'	System	04 Sep 2020 21:31:40
User entered 'No (N)'	System	04 Sep 2020 21:31:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:34', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'af20d870-fb8e-488a-a94a-5035fb80f4e0'	System	04 Sep 2020 21:31:40
User entered 'No (N)'	System	04 Sep 2020 21:31:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:39', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'af20d870-fb8e-488a-a94a-5035fb80f4e0'	System	04 Sep 2020 21:31:40
User entered 'None (1)'	System	04 Sep 2020 21:31:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:43', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'af20d870-fb8e-488a-a94a-5035fb80f4e0'	System	04 Sep 2020 21:31:40
User entered '04 Sep 2020 16:31'	System	04 Sep 2020 21:31:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 16:15'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 18:45'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0d43f1df-ae7b-404d-ab38-e72cb1d19c52'	System	05 Sep 2020 08:54:58
User entered 'None (1)'	System	05 Sep 2020 08:54:58

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:45', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0d43f1df-ae7b-404d-ab38-e72cb1d19c52'	System	05 Sep 2020 08:54:58
User entered 'No (N)'	System	05 Sep 2020 08:54:58

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:51', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0d43f1df-ae7b-404d-ab38-e72cb1d19c52'	System	05 Sep 2020 08:54:58
User entered 'No (N)'	System	05 Sep 2020 08:54:58

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:54:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0d43f1df-ae7b-404d-ab38-e72cb1d19c52'	System	05 Sep 2020 08:54:58
User entered 'None (1)'	System	05 Sep 2020 08:54:58

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0d43f1df-ae7b-404d-ab38-e72cb1d19c52'	System	05 Sep 2020 08:54:58
User entered '05 Sep 2020 03:55'	System	05 Sep 2020 08:54:58

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 2'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '76bd271f-0a63-48a2-8ade-85dfb5b69121'	System	05 Sep 2020 23:28:06
User entered 'None (1)'	System	05 Sep 2020 23:28:06

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '76bd271f-0a63-48a2-8ade-85dfb5b69121'	System	05 Sep 2020 23:28:06
User entered 'No (N)'	System	05 Sep 2020 23:28:06

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '76bd271f-0a63-48a2-8ade-85dfb5b69121'	System	05 Sep 2020 23:28:06
User entered 'No (N)'	System	05 Sep 2020 23:28:06

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:27:58', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '76bd271f-0a63-48a2-8ade-85dfb5b69121'	System	05 Sep 2020 23:28:06
User entered 'None (1)'	System	05 Sep 2020 23:28:06

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '76bd271f-0a63-48a2-8ade-85dfb5b69121'	System	05 Sep 2020 23:28:06
User entered '05 Sep 2020 18:28'	System	05 Sep 2020 23:28:06

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 3'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e47c766d-f0ca-4a00-a82b-5abdfd4c7bd1'	System	06 Sep 2020 22:08:28
User entered 'None (1)'	System	06 Sep 2020 22:08:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e47c766d-f0ca-4a00-a82b-5abdfd4c7bd1'	System	06 Sep 2020 22:08:28
User entered 'No (N)'	System	06 Sep 2020 22:08:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:07:53', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e47c766d-f0ca-4a00-a82b-5abdfd4c7bd1'	System	06 Sep 2020 22:08:28
User entered 'No (N)'	System	06 Sep 2020 22:08:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e47c766d-f0ca-4a00-a82b-5abdfd4c7bd1'	System	06 Sep 2020 22:08:28
User entered 'None (1)'	System	06 Sep 2020 22:08:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:27', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e47c766d-f0ca-4a00-a82b-5abdfd4c7bd1'	System	06 Sep 2020 22:08:28
User entered '06 Sep 2020 17:08'	System	06 Sep 2020 22:08:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 4'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '184497d3-f0f9-459d-9ca9-58de6f2add90'	System	07 Sep 2020 20:23:08
User entered 'None (1)'	System	07 Sep 2020 20:23:08

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:53', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '184497d3-f0f9-459d-9ca9-58de6f2add90'	System	07 Sep 2020 20:23:08
User entered 'No (N)'	System	07 Sep 2020 20:23:08

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:22:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '184497d3-f0f9-459d-9ca9-58de6f2add90'	System	07 Sep 2020 20:23:08
User entered 'No (N)'	System	07 Sep 2020 20:23:08

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '184497d3-f0f9-459d-9ca9-58de6f2add90'	System	07 Sep 2020 20:23:08
User entered 'None (1)'	System	07 Sep 2020 20:23:08

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '184497d3-f0f9-459d-9ca9-58de6f2add90'	System	07 Sep 2020 20:23:08
User entered '07 Sep 2020 15:23'	System	07 Sep 2020 20:23:08

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 5'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9d71490f-9235-4e67-9712-ed6e7d2e332f'	System	08 Sep 2020 22:29:40
User entered 'None (1)'	System	08 Sep 2020 22:29:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9d71490f-9235-4e67-9712-ed6e7d2e332f'	System	08 Sep 2020 22:29:40
User entered 'No (N)'	System	08 Sep 2020 22:29:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9d71490f-9235-4e67-9712-ed6e7d2e332f'	System	08 Sep 2020 22:29:40
User entered 'No (N)'	System	08 Sep 2020 22:29:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9d71490f-9235-4e67-9712-ed6e7d2e332f'	System	08 Sep 2020 22:29:40
User entered 'None (1)'	System	08 Sep 2020 22:29:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:38', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9d71490f-9235-4e67-9712-ed6e7d2e332f'	System	08 Sep 2020 22:29:40
User entered '08 Sep 2020 17:29'	System	08 Sep 2020 22:29:40

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 6'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '97bf1dd8-ed63-41bf-95cb-804fac0f33ac'	System	09 Sep 2020 21:05:52
User entered 'None (1)'	System	09 Sep 2020 21:05:52

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:38', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '97bf1dd8-ed63-41bf-95cb-804fac0f33ac'	System	09 Sep 2020 21:05:52
User entered 'No (N)'	System	09 Sep 2020 21:05:52

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '97bf1dd8-ed63-41bf-95cb-804fac0f33ac'	System	09 Sep 2020 21:05:52
User entered 'No (N)'	System	09 Sep 2020 21:05:52

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '97bf1dd8-ed63-41bf-95cb-804fac0f33ac'	System	09 Sep 2020 21:05:52
User entered 'None (1)'	System	09 Sep 2020 21:05:52

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '97bf1dd8-ed63-41bf-95cb-804fac0f33ac'	System	09 Sep 2020 21:05:52
User entered '09 Sep 2020 16:05'	System	09 Sep 2020 21:05:52

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 7'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd42d720d-986f-4145-acba-9a907b249cfc'	System	10 Sep 2020 17:44:28
User entered 'None (1)'	System	10 Sep 2020 17:44:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:07', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd42d720d-986f-4145-acba-9a907b249cfc'	System	10 Sep 2020 17:44:28
User entered 'No (N)'	System	10 Sep 2020 17:44:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd42d720d-986f-4145-acba-9a907b249cfc'	System	10 Sep 2020 17:44:28
User entered 'No (N)'	System	10 Sep 2020 17:44:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd42d720d-986f-4145-acba-9a907b249cfc'	System	10 Sep 2020 17:44:28
User entered 'None (1)'	System	10 Sep 2020 17:44:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:27', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd42d720d-986f-4145-acba-9a907b249cfc'	System	10 Sep 2020 17:44:28
User entered '10 Sep 2020 12:44'	System	10 Sep 2020 17:44:28

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:50', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:31:58', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:32:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'None (0)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:32:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered 'No (N)'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-04T16:32:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '63d3f9b2-1763-49b3-b9d5-be8db733a31c'	System	04 Sep 2020 21:32:11
User entered '04 Sep 2020 16:32'	System	04 Sep 2020 21:32:11

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 16:15'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 18:45'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'None (0)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered 'No (N)'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T03:55:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '56d8e71c-774a-40fe-a10d-ab185b667820'	System	05 Sep 2020 08:55:32
User entered '05 Sep 2020 03:55'	System	05 Sep 2020 08:55:32

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 2'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:14', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'None (0)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered 'No (N)'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-05T18:28:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'ca395113-6b59-4f01-9547-500d537b4661'	System	05 Sep 2020 23:28:35
User entered '05 Sep 2020 18:28'	System	05 Sep 2020 23:28:35

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 3'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:43', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:50', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'None (0)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:08:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered 'No (N)'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-06T17:09:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b98166e1-67af-40cd-9988-abb3b53595c6'	System	06 Sep 2020 22:09:04
User entered '06 Sep 2020 17:09'	System	06 Sep 2020 22:09:04

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 4'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:14', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:17', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:20', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'None (0)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered 'No (N)'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-07T15:23:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '88540265-278e-4e04-a3db-916b817a1735'	System	07 Sep 2020 20:23:38
User entered '07 Sep 2020 15:23'	System	07 Sep 2020 20:23:38

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 5'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:45', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:47', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:50', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:53', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:29:59', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'None (0)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:30:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered 'No (N)'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-08T17:30:11', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '11ca96e3-cdb0-4759-bba4-48d83a6a18d1'	System	08 Sep 2020 22:30:12
User entered '08 Sep 2020 17:30'	System	08 Sep 2020 22:30:12

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 6'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:05:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:03', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'None (0)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered 'No (N)'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-09T16:06:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '4d96d83e-201e-46b7-9bef-9f145b92fa27'	System	09 Sep 2020 21:06:23
User entered '09 Sep 2020 16:06'	System	09 Sep 2020 21:06:23

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	04 Sep 2020 21:01:18
User entered 'Day 7'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:34', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:39', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:43', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:46', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:44:53', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'None (0)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:45:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered 'No (N)'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-09-10T12:45:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '77931e1d-cbc7-4d26-b4e2-bcf399b7df6d'	System	10 Sep 2020 17:45:17
User entered '10 Sep 2020 12:45'	System	10 Sep 2020 17:45:17

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:01:18

US3062157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:01:18

US3062157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:21:21
User entered 'Yes (Y)'	Colton King (b) (4)	11 Sep 2020 19:36:20
	(b) (4)	

US3062157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:21:21
User entered '11 Sep 2020'	Colton King (b) (4)	11 Sep 2020 19:36:20
	(b) (4)	

US3062157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:21:21
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	11 Sep 2020 19:36:20
	(b) (4)	

US3062157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:21:21
User entered empty.	Colton King (b) (4)	11 Sep 2020 19:36:20
	(b) (4)	

US3062157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:21:26
User entered 'Yes (Y)'	Colton King (b) (4)	11 Sep 2020 19:36:28
	(b) (4)	

US3062157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	11 Sep 2020 19:36:28

US3062157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:00
User entered 'Yes (Y)'	Colton King (b) (4)	18 Sep 2020 22:08:03
	(b) (4)	

US3062157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:00
User entered '18 Sep 2020'	Colton King (b) (4)	18 Sep 2020 22:08:03
	(b) (4)	

US3062157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:00
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	18 Sep 2020 22:08:03
	(b) (4)	

US3062157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:00
User entered empty.	Colton King (b) (4)	18 Sep 2020 22:08:03
	(b) (4)	

US3062157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:04
User entered 'Yes (Y)'	Colton King (b) (4)	18 Sep 2020 22:08:09
	(b) (4)	

US3062157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	18 Sep 2020 22:08:09

US3062157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:17
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 20:36:45
	(b) (4)	

US3062157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:17
User entered '25 Sep 2020'	Colton King (b) (4)	25 Sep 2020 20:36:45
	(b) (4)	

US3062157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:17
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	25 Sep 2020 20:36:45
	(b) (4)	

US3062157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:17
User entered empty.	Colton King (b) (4)	25 Sep 2020 20:36:45
	(b) (4)	

US3062157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:20
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 20:36:48
	(b) (4)	

US3062157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	25 Sep 2020 20:36:48

US3062157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:52:17
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 20:05:27
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:52:17
User entered '01 Oct 2020'	Janna Martinez (b) (4)	01 Oct 2020 20:05:27
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:52:17
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	01 Oct 2020 20:05:27
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'VISIT3'	System	01 Oct 2020 20:05:27

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '01 Oct 2020'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '14:19'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '01 Oct 2020 14:19'	System	01 Oct 2020 20:05:55

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '98.2' F	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered empty.	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '51'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'bpm'	System	01 Oct 2020 20:05:55

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '16'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'breaths/min'	System	01 Oct 2020 20:05:55

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '128'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	01 Oct 2020 20:05:55

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:58:52
User entered '84'	Janna Martinez (b) (4)	01 Oct 2020 20:05:55
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'mmHg'	System	01 Oct 2020 20:05:55

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18

US3062157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18

US3062157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:02
User entered 'No (N)'	Janna Martinez (b) (4)	01 Oct 2020 20:06:02
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:02
User entered empty.	Janna Martinez (b) (4)	01 Oct 2020 20:06:02
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:14
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 20:06:13
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:14
User entered '01 Oct 2020'	Janna Martinez (b) (4)	01 Oct 2020 20:06:13
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:14
User entered '14:33'	Janna Martinez (b) (4)	01 Oct 2020 20:06:13
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered '01 Oct 2020 14:33'	System	01 Oct 2020 20:06:13

US3062157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:35:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:59:23
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 20:06:15
	(b) (4)	

US3062157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	01 Oct 2020 20:06:15

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 64'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-09T10:57:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0e46c0bf-1988-4f3d-8fbc-4e063fe5d6da'	System	09 Oct 2020 15:57:47
User entered 'No (N)'	System	09 Oct 2020 15:57:47

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-09T10:57:39', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0e46c0bf-1988-4f3d-8fbc-4e063fe5d6da'	System	09 Oct 2020 15:57:47
User entered 'No (N)'	System	09 Oct 2020 15:57:47

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-09T10:57:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0e46c0bf-1988-4f3d-8fbc-4e063fe5d6da'	System	09 Oct 2020 15:57:47
User entered '09 Oct 2020 10:57:48'	System	09 Oct 2020 15:57:47

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 71'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-16T15:20:47', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bd49e3b2-8554-4167-b1db-43b679f51cbc'	System	16 Oct 2020 20:21:37
User entered 'Yes (Y)'	System	16 Oct 2020 20:21:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-16T15:21:08', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bd49e3b2-8554-4167-b1db-43b679f51cbc'	System	16 Oct 2020 20:21:37
User entered 'No (N)'	System	16 Oct 2020 20:21:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-16T15:21:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bd49e3b2-8554-4167-b1db-43b679f51cbc'	System	16 Oct 2020 20:21:37
User entered 'No (N)'	System	16 Oct 2020 20:21:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-16T15:21:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bd49e3b2-8554-4167-b1db-43b679f51cbc'	System	16 Oct 2020 20:21:37
User entered 'No (N)'	System	16 Oct 2020 20:21:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-16T15:21:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bd49e3b2-8554-4167-b1db-43b679f51cbc'	System	16 Oct 2020 20:21:37
User entered '16 Oct 2020 15:21:32'	System	16 Oct 2020 20:21:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 78'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-21T21:27:41', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '844d1471-c94b-4a73-8e64-ec29ac342998'	System	22 Oct 2020 02:27:49
User entered 'No (N)'	System	22 Oct 2020 02:27:49

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-21T21:27:47', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '844d1471-c94b-4a73-8e64-ec29ac342998'	System	22 Oct 2020 02:27:49
User entered 'No (N)'	System	22 Oct 2020 02:27:49

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-10-21T21:27:51', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '844d1471-c94b-4a73-8e64-ec29ac342998'	System	22 Oct 2020 02:27:49
User entered '21 Oct 2020 21:27:51'	System	22 Oct 2020 02:27:49

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 92'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-04T21:25:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '43282f05-0072-425f-95de-2ac5bad95aab'	System	05 Nov 2020 03:25:36
User entered 'No (N)'	System	05 Nov 2020 03:25:36

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-04T21:25:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '43282f05-0072-425f-95de-2ac5bad95aab'	System	05 Nov 2020 03:25:36
User entered 'No (N)'	System	05 Nov 2020 03:25:36

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-04T21:25:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '43282f05-0072-425f-95de-2ac5bad95aab'	System	05 Nov 2020 03:25:36
User entered '04 Nov 2020 21:25:33'	System	05 Nov 2020 03:25:36

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 99'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-11T19:29:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e87ee618-b78b-4bd8-bcca-0db97545cbe2'	System	12 Nov 2020 01:29:37
User entered 'No (N)'	System	12 Nov 2020 01:29:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-11T19:29:20', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e87ee618-b78b-4bd8-bcca-0db97545cbe2'	System	12 Nov 2020 01:29:37
User entered 'Yes (Y)'	System	12 Nov 2020 01:29:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-11T19:29:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e87ee618-b78b-4bd8-bcca-0db97545cbe2'	System	12 Nov 2020 01:29:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 01:29:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-11T19:29:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e87ee618-b78b-4bd8-bcca-0db97545cbe2'	System	12 Nov 2020 01:29:37
User entered '11 Nov 2020 19:29:33'	System	12 Nov 2020 01:29:37

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered 'Day 106'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-18T06:04:28', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b6f311ff-ca4d-4ebd-a9c9-5659ad17d7e8'	System	18 Nov 2020 12:04:39
User entered 'No (N)'	System	18 Nov 2020 12:04:39

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-18T06:04:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b6f311ff-ca4d-4ebd-a9c9-5659ad17d7e8'	System	18 Nov 2020 12:04:39
User entered 'No (N)'	System	18 Nov 2020 12:04:39

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-18T06:04:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b6f311ff-ca4d-4ebd-a9c9-5659ad17d7e8'	System	18 Nov 2020 12:04:39
User entered '18 Nov 2020 06:04:37'	System	18 Nov 2020 12:04:39

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 21:32:17

US3062157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:07:04
Data entry locked.	System	07 Aug 2020 21:32:17
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 21:32:17

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2020-11-29T19:51:27', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd7c7bcb0-c2ba-4d16-a090-e78f79809fe8'	System	30 Nov 2020 01:51:36
User entered 'No (N)'	System	30 Nov 2020 01:51:36

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2020-11-29T19:51:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd7c7bcb0-c2ba-4d16-a090-e78f79809fe8'	System	30 Nov 2020 01:51:36
User entered 'No (N)'	System	30 Nov 2020 01:51:36

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-11-29T19:51:37', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'd7c7bcb0-c2ba-4d16-a090-e78f79809fe8'	System	30 Nov 2020 01:51:36
User entered '29 Nov 2020 19:51:37'	System	30 Nov 2020 01:51:36

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2020-12-10T17:19:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '46ab425f-1620-4464-a999-efd2ff33d2e0'	System	10 Dec 2020 23:19:34
User entered 'No (N)'	System	10 Dec 2020 23:19:34

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2020-12-10T17:19:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '46ab425f-1620-4464-a999-efd2ff33d2e0'	System	10 Dec 2020 23:19:34
User entered 'No (N)'	System	10 Dec 2020 23:19:34

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-12-10T17:19:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '46ab425f-1620-4464-a999-efd2ff33d2e0'	System	10 Dec 2020 23:19:34
User entered '10 Dec 2020 17:19:31'	System	10 Dec 2020 23:19:34

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2020-12-13T01:59:18', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1cebc32c-f645-4555-9085-8d42dde302eb'	System	13 Dec 2020 07:59:25
User entered 'No (N)'	System	13 Dec 2020 07:59:25

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2020-12-13T01:59:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1cebc32c-f645-4555-9085-8d42dde302eb'	System	13 Dec 2020 07:59:25
User entered 'No (N)'	System	13 Dec 2020 07:59:25

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-12-13T01:59:25', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '1cebc32c-f645-4555-9085-8d42dde302eb' User entered '13 Dec 2020 01:59:25'	System	13 Dec 2020 07:59:25
	System	13 Dec 2020 07:59:25

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2020-12-20T02:00:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9ab6a920-523d-4373-8137-f070697f71b4'	System	20 Dec 2020 08:00:37
User entered 'No (N)'	System	20 Dec 2020 08:00:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2020-12-20T02:00:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9ab6a920-523d-4373-8137-f070697f71b4'	System	20 Dec 2020 08:00:37
User entered 'No (N)'	System	20 Dec 2020 08:00:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-12-20T02:00:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '9ab6a920-523d-4373-8137-f070697f71b4'	System	20 Dec 2020 08:00:37
User entered '20 Dec 2020 02:00:36'	System	20 Dec 2020 08:00:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2020-12-31T02:53:32', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '632062e0-c0fe-41aa-80b5-bdb84e7e76cb'	System	31 Dec 2020 08:53:46
User entered 'No (N)'	System	31 Dec 2020 08:53:46

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2020-12-31T02:53:40', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '632062e0-c0fe-41aa-80b5-bdb84e7e76cb'	System	31 Dec 2020 08:53:46
User entered 'No (N)'	System	31 Dec 2020 08:53:46

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2020-12-31T02:53:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '632062e0-c0fe-41aa-80b5-bdb84e7e76cb' User entered '31 Dec 2020 02:53:44'	System	31 Dec 2020 08:53:46
	System	31 Dec 2020 08:53:46

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-01-03T00:32:51', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '810c4c4e-0d67-4f87-9e10-e70eb2975721'	System	03 Jan 2021 06:32:58
User entered 'No (N)'	System	03 Jan 2021 06:32:58

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-01-03T00:32:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '810c4c4e-0d67-4f87-9e10-e70eb2975721'	System	03 Jan 2021 06:32:58
User entered 'No (N)'	System	03 Jan 2021 06:32:58

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-01-03T00:32:59', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '810c4c4e-0d67-4f87-9e10-e70eb2975721'	System	03 Jan 2021 06:32:58
User entered '03 Jan 2021 00:32:59'	System	03 Jan 2021 06:32:58

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-01-14T13:47:10', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf542dac-d3ed-47e6-bf9b-499c2dd242dd'	System	14 Jan 2021 19:47:19
User entered 'No (N)'	System	14 Jan 2021 19:47:19

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-01-14T13:47:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf542dac-d3ed-47e6-bf9b-499c2dd242dd'	System	14 Jan 2021 19:47:19
User entered 'No (N)'	System	14 Jan 2021 19:47:19

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-01-14T13:47:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'bf542dac-d3ed-47e6-bf9b-499c2dd242dd'	System	14 Jan 2021 19:47:19
User entered '14 Jan 2021 13:47:15'	System	14 Jan 2021 19:47:19

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-01-17T06:03:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'cbeee26d-4366-4a28-aaa4-b4b12e005884'	System	17 Jan 2021 12:03:37
User entered 'No (N)'	System	17 Jan 2021 12:03:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-01-17T06:03:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'cbeee26d-4366-4a28-aaa4-b4b12e005884'	System	17 Jan 2021 12:03:37
User entered 'No (N)'	System	17 Jan 2021 12:03:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-01-17T06:03:33', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'cbeee26d-4366-4a28-aaa4-b4b12e005884' User entered '17 Jan 2021 06:03:33'	System	17 Jan 2021 12:03:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-01-27T10:17:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '80a56994-0fd3-4892-9ef0-80f91d05baf4'	System	27 Jan 2021 16:17:47
User entered 'No (N)'	System	27 Jan 2021 16:17:47

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-01-27T10:17:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '80a56994-0fd3-4892-9ef0-80f91d05baf4'	System	27 Jan 2021 16:17:47
User entered 'No (N)'	System	27 Jan 2021 16:17:47

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-01-27T10:17:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '80a56994-0fd3-4892-9ef0-80f91d05baf4' User entered '27 Jan 2021 10:17:44'	System	27 Jan 2021 16:17:47
	System	27 Jan 2021 16:17:47

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-01-31T00:46:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '427876e0-8847-4caf-8e9e-d602d1de7ab3'	System	31 Jan 2021 06:47:06
User entered 'No (N)'	System	31 Jan 2021 06:47:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-01-31T00:46:56', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '427876e0-8847-4caf-8e9e-d602d1de7ab3'	System	31 Jan 2021 06:47:06
User entered 'No (N)'	System	31 Jan 2021 06:47:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-01-31T00:47:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '427876e0-8847-4caf-8e9e-d602d1de7ab3'	System	31 Jan 2021 06:47:06
User entered '31 Jan 2021 00:47:05'	System	31 Jan 2021 06:47:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-02-09T14:44:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2f6a8f1c-811e-4324-aebf-f1811b2fdb90'	System	09 Feb 2021 20:44:10
User entered 'No (N)'	System	09 Feb 2021 20:44:10

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-02-09T14:44:09', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2f6a8f1c-811e-4324-aebf-f1811b2fdb90'	System	09 Feb 2021 20:44:10
User entered 'No (N)'	System	09 Feb 2021 20:44:10

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-02-09T14:44:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '2f6a8f1c-811e-4324-aebf-f1811b2fdb90'	System	09 Feb 2021 20:44:10
User entered '09 Feb 2021 14:44:12'	System	09 Feb 2021 20:44:10

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-02-14T14:30:26', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b5910aaf-61e9-4f0c-809e-527d5c69b952'	System	14 Feb 2021 20:32:37
User entered 'No (N)'	System	14 Feb 2021 20:32:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-02-14T14:31:19', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b5910aaf-61e9-4f0c-809e-527d5c69b952'	System	14 Feb 2021 20:32:37
User entered 'No (N)'	System	14 Feb 2021 20:32:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-02-14T14:32:35', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'b5910aaf-61e9-4f0c-809e-527d5c69b952'	System	14 Feb 2021 20:32:37
User entered '14 Feb 2021 14:32:35'	System	14 Feb 2021 20:32:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-02-22T00:57:43', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a3d7baf4-bcb2-4c1a-86a6-f6da9fcef9da'	System	22 Feb 2021 06:57:53
User entered 'No (N)'	System	22 Feb 2021 06:57:53

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-02-22T00:57:47', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a3d7baf4-bcb2-4c1a-86a6-f6da9fcef9da'	System	22 Feb 2021 06:57:53
User entered 'No (N)'	System	22 Feb 2021 06:57:53

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-02-22T00:57:50', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'a3d7baf4-bcb2-4c1a-86a6-f6da9fcef9da'	System	22 Feb 2021 06:57:53
User entered '22 Feb 2021 00:57:50'	System	22 Feb 2021 06:57:53

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-03-01T17:30:23', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0805dcab-1333-444a-8cd6-c4c4cd6c1e39'	System	01 Mar 2021 23:30:30
User entered 'No (N)'	System	01 Mar 2021 23:30:30

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-03-01T17:30:27', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0805dcab-1333-444a-8cd6-c4c4cd6c1e39'	System	01 Mar 2021 23:30:30
User entered 'No (N)'	System	01 Mar 2021 23:30:30

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-01T17:30:30', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '0805dcab-1333-444a-8cd6-c4c4cd6c1e39'	System	01 Mar 2021 23:30:30
User entered '01 Mar 2021 17:30:30'	System	01 Mar 2021 23:30:30

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-03-09T14:22:36', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '347e67d1-2cf5-4e4f-bbaa-e5b7668533d4'	System	09 Mar 2021 20:22:44
User entered 'No (N)'	System	09 Mar 2021 20:22:44

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-03-09T14:22:41', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '347e67d1-2cf5-4e4f-bbaa-e5b7668533d4'	System	09 Mar 2021 20:22:44
User entered 'No (N)'	System	09 Mar 2021 20:22:44

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-09T14:22:44', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '347e67d1-2cf5-4e4f-bbaa-e5b7668533d4' User entered '09 Mar 2021 14:22:44'	System	09 Mar 2021 20:22:44
	System	09 Mar 2021 20:22:44

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-03-16T13:33:49', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '68877c2b-815f-4842-b764-a40e758b7575'	System	16 Mar 2021 18:34:00
User entered 'No (N)'	System	16 Mar 2021 18:34:00

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-03-16T13:33:54', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '68877c2b-815f-4842-b764-a40e758b7575'	System	16 Mar 2021 18:34:00
User entered 'No (N)'	System	16 Mar 2021 18:34:00

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-16T13:33:57', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '68877c2b-815f-4842-b764-a40e758b7575'	System	16 Mar 2021 18:34:00
User entered '16 Mar 2021 13:33:57'	System	16 Mar 2021 18:34:00

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-03-22T23:27:58', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '37455da5-552f-4c74-8c50-3459476c9edf'	System	23 Mar 2021 04:28:06
User entered 'No (N)'	System	23 Mar 2021 04:28:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-03-22T23:28:01', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '37455da5-552f-4c74-8c50-3459476c9edf'	System	23 Mar 2021 04:28:06
User entered 'No (N)'	System	23 Mar 2021 04:28:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-22T23:28:06', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '37455da5-552f-4c74-8c50-3459476c9edf'	System	23 Mar 2021 04:28:06
User entered '22 Mar 2021 23:28:06'	System	23 Mar 2021 04:28:06

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-03-30T11:53:13', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '433f5af2-bce4-4b4c-a1fb-ade224a48eed'	System	30 Mar 2021 16:54:21
User entered 'No (N)'	System	30 Mar 2021 16:54:21

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-03-30T11:53:22', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '433f5af2-bce4-4b4c-a1fb-ade224a48eed'	System	30 Mar 2021 16:54:21
User entered 'No (N)'	System	30 Mar 2021 16:54:21

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-30T11:53:55', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '433f5af2-bce4-4b4c-a1fb-ade224a48eed' User entered '30 Mar 2021 11:53:55'	System	30 Mar 2021 16:54:21
	System	30 Mar 2021 16:54:21

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-04-05T19:53:48', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '917df009-d3be-4dd7-a8d9-162ef41965a9'	System	06 Apr 2021 00:54:37
User entered 'No (N)'	System	06 Apr 2021 00:54:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-04-05T19:54:31', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '917df009-d3be-4dd7-a8d9-162ef41965a9'	System	06 Apr 2021 00:54:37
User entered 'No (N)'	System	06 Apr 2021 00:54:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-04-05T19:54:38', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '917df009-d3be-4dd7-a8d9-162ef41965a9'	System	06 Apr 2021 00:54:37
User entered '05 Apr 2021 19:54:38'	System	06 Apr 2021 00:54:37

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-04-13T18:40:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '597d3f25-b7eb-4837-8d59-6546f13d4956'	System	13 Apr 2021 23:40:13
User entered 'No (N)'	System	13 Apr 2021 23:40:13

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-04-13T18:40:10', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '597d3f25-b7eb-4837-8d59-6546f13d4956'	System	13 Apr 2021 23:40:13
User entered 'No (N)'	System	13 Apr 2021 23:40:13

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-04-13T18:40:13', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '597d3f25-b7eb-4837-8d59-6546f13d4956'	System	13 Apr 2021 23:40:13
User entered '13 Apr 2021 18:40:13'	System	13 Apr 2021 23:40:13

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-04-20T11:47:02', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36b24c97-40c0-408f-872b-9b95349bbdb5'	System	20 Apr 2021 16:47:17
User entered 'No (N)'	System	20 Apr 2021 16:47:17

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-04-20T11:47:05', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36b24c97-40c0-408f-872b-9b95349bbdb5'	System	20 Apr 2021 16:47:17
User entered 'No (N)'	System	20 Apr 2021 16:47:17

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-04-20T11:47:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '36b24c97-40c0-408f-872b-9b95349bbdb5'	System	20 Apr 2021 16:47:17
User entered '20 Apr 2021 11:47:12'	System	20 Apr 2021 16:47:17

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-04-27T03:50:12', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '945743d8-ab76-46cc-888a-1f68a06da74c'	System	27 Apr 2021 08:50:20
User entered 'No (N)'	System	27 Apr 2021 08:50:20

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-04-27T03:50:15', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '945743d8-ab76-46cc-888a-1f68a06da74c'	System	27 Apr 2021 08:50:20
User entered 'No (N)'	System	27 Apr 2021 08:50:20

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-04-27T03:50:20', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '945743d8-ab76-46cc-888a-1f68a06da74c'	System	27 Apr 2021 08:50:20
User entered '27 Apr 2021 03:50:20'	System	27 Apr 2021 08:50:20

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[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 (cb108e46fb7c6c8e)', Time: '2021-05-03T03:14:21', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '27886c0e-f1ae-458d-97ce-8c77c4d64f62'	System	03 May 2021 08:14:33
User entered 'No (N)'	System	03 May 2021 08:14:33

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

Have you been exposed to someone with 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 (cb108e46fb7c6c8e)', Time: '2021-05-03T03:14:24', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '27886c0e-f1ae-458d-97ce-8c77c4d64f62'	System	03 May 2021 08:14:33
User entered 'No (N)'	System	03 May 2021 08:14:33

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-05-03T03:14:29', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: '27886c0e-f1ae-458d-97ce-8c77c4d64f62'	System	03 May 2021 08:14:33
User entered '03 May 2021 03:14:29'	System	03 May 2021 08:14:33

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:20:05

US3062157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:20:05
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:20:05

US3062157

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:06:44

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 23:04:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-01T17:30:42', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e35e35cf-42f0-4ad6-b913-2c89a8e6bcf0'	System	01 Mar 2021 23:30:53
User entered 'No (N)'	System	01 Mar 2021 23:30:53

US3062157

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:06:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:04:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cb108e46fb7c6c8e)', Time: '2021-03-01T17:30:52', User OID: 'PatientReportedOutcome (US3062157)', ODM File OID: 'e35e35cf-42f0-4ad6-b913-2c89a8e6bcf0'	System	01 Mar 2021 23:30:53
User entered '01 Mar 2021 17:30:52'	System	01 Mar 2021 23:30:53

US3062157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:47:43
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Oct 2020 15:49:00
	(b) (4)	

US3062157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:47:43
User entered '28 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 15:49:00
	(b) (4)	

US3062157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:47:43
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	29 Oct 2020 15:49:00
	(b) (4)	

US3062157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:47:43
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 15:49:00
	(b) (4)	

US3062157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:47:49
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Oct 2020 15:48:51
	(b) (4)	

US3062157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:18
User entered 'I'	System	29 Oct 2020 15:48:51

US3062157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:23
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 22:02:38
	(b) (4)	

US3062157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:23
User entered '30 Nov 2020'	Riley King (b) (4)	30 Nov 2020 22:02:38
	(b) (4)	

US3062157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:23
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	30 Nov 2020 22:02:38
	(b) (4)	

US3062157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:23
User entered empty.	Riley King (b) (4)	30 Nov 2020 22:02:38
	(b) (4)	

US3062157

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:29
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 22:02:42
	(b) (4)	

US3062157

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User entered 'I'	System	30 Nov 2020 22:02:42

US3062157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:37:12
User entered 'Yes (Y)'	Colton King (b) (4)	30 Dec 2020 22:27:22

US3062157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:37:12
User closed query 'please complete D179 tabs' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 22:31:26
Query 'please complete D179 tabs' answered with 'DATA CORRECTED' (Site from CRA).	Janna Martinez (b) (4)	22 Feb 2021 22:43:16
	(b) (4)	
User opened query 'please complete D179 tabs' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 17:32:35
User entered '30 Dec 2020'	Colton King (b) (4)	30 Dec 2020 22:27:22
	(b) (4)	

US3062157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:37:12
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	30 Dec 2020 22:27:22
	(b) (4)	

US3062157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:37:12
User entered empty.	Colton King (b) (4)	30 Dec 2020 22:27:22
	(b) (4)	

US3062157

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:37:19
User entered 'Yes (Y)'	Colton King (b) (4)	30 Dec 2020 22:27:28
	(b) (4)	

US3062157

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User entered 'I'	System	30 Dec 2020 22:27:28

US3062157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:39:09
User entered 'Yes (Y)'	Janna Martinez (b) (4)	22 Feb 2021 22:42:47

US3062157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 21:54:06
User closed query 'please verify as 3Feb21 per source' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:54:01
Query 'please verify as 3Feb21 per source' answered with 'updated per source. ' (Site from CRA).	Cayla Lawless (b) (4)	11 Mar 2021 18:32:01
	(b) (4)	
User entered '03 Feb 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	11 Mar 2021 18:31:54
	(b) (4)	
User opened query 'please verify as 3Feb21 per source' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 16:39:07
User entered '04 Feb 2021'	Janna Martinez (b) (4)	22 Feb 2021 22:42:47
	(b) (4)	

US3062157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:39:12
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	22 Feb 2021 22:42:47

US3062157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:39:14
User entered empty.	Janna Martinez (b) (4)	22 Feb 2021 22:42:47
	(b) (4)	

US3062157

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:10:15
User entered 'Yes (Y)'	Janna Martinez (b) (4)	22 Feb 2021 22:42:53

US3062157

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:04:15
User entered 'I'	System	22 Feb 2021 22:42:53

US3062157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:16:44
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data corrected' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:06:41
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:39:08
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:40:22
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:14:28
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:40:22
User entered '25 Feb 2021'	Colton King (b) (4)	25 Feb 2021 22:14:28
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[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 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:40:22
User entered 'Clinic (Clinic)'	Colton King (b) (4)	25 Feb 2021 22:14:28
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User entered 'VISIT4'	System	25 Feb 2021 22:14:28

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '25 Feb 2021'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '13:10'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
User entered '25 Feb 2021 13:10'	System	30 Mar 2021 19:06:23

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '98.0' F	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '91'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
User entered 'bpm'	System	30 Mar 2021 19:06:23

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
User entered 'breaths/min'	System	30 Mar 2021 19:06:23

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
User entered '126'	(b) (4) Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
User entered 'mmHg'	System	30 Mar 2021 19:06:23

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered '91'	Janna Martinez (b) (4)	30 Mar 2021 19:06:23
	(b) (4)	

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46
User entered 'mmHg'	System	30 Mar 2021 19:06:23

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46

US3062157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:46

US3062157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:47:11
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:32:32
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	20 Apr 2021 15:44:18
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	20 Apr 2021 15:43:57
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Apr 2021 15:43:57
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:41:56
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:41:56

US3062157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' answered with 'Visit 4- only symptom directed is required OL Day 29- investigator is required to assess lymph nodes and injection arm ie part of a physical. If visit 4 did not require lab but Ol D29 did, we would document as such as each tab is visit/protocol derived. ' (Site from DM).	marissa Mueller (b) (4)	02 Apr 2021 13:34:36
	(b) (4)	
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:39:12
User closed query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:39:12
Query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' answered with 'per protocol, px not required at this visit. This would be the same if immunogenicity was drawn at one and not the other per protocol. Correct as entered' (Site from DM).	marissa Mueller (b) (4)	31 Mar 2021 15:15:54
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Was the physical examination performed?

Audit	User	Time (GMT)
User opened query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:00:51
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:00:51
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'data correct as entered as Physical is not required for visit 4 but is required for OL-D29' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:04:36
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:39:29
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:41:53
User entered 'No (N)'	Colton King (b) (4)	25 Feb 2021 22:14:33

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:47:11
DataPoint Un-verified.	marissa Mueller (b) (4)	20 Apr 2021 15:43:57
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	20 Apr 2021 15:43:57
	(b) (4)	
User entered '25 Feb 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Apr 2021 15:43:57
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User closed query 'please complete Immunogenicity tab at 1324 per source' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:53:07
Query 'please complete Immunogenicity tab at 1324 per source' answered with 'updated per source. ' (Site from CRA).	Cayla Lawless (b) (4)	11 Mar 2021 18:30:14
	(b) (4)	
User opened query 'please complete Immunogenicity tab at 1324 per source' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 16:44:07
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:41:53
	(b) (4)	
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:14:33
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 21:53:01
User entered 'Yes (Y)'	Cayla Lawless (b) (4)	11 Mar 2021 18:29:33

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 21:53:01
User entered '25 Feb 2021'	Cayla Lawless (b) (4)	11 Mar 2021 18:29:33

US3062157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 21:53:01
User entered '13:24'	Cayla Lawless (b) (4)	11 Mar 2021 18:29:33

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User entered '25 Feb 2021 13:24'	System	11 Mar 2021 18:29:33

US3062157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:43:14
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:14:39

US3062157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:47
User entered 'I'	System	25 Feb 2021 22:14:39

US3062157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:45
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 13:27:24
	(b) (4)	

US3062157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:45
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1 Apr 2021'	Colton King (b) (4)	05 Apr 2021 13:27:24
	(b) (4)	

US3062157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:45
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	05 Apr 2021 13:27:24
	(b) (4)	

US3062157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:45
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User entered empty.	(b) (4) Colton King (b) (4)	05 Apr 2021 13:27:24

US3062157

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:18:52
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 13:27:49
	(b) (4)	

US3062157

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 13:27:49

US3062157

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

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:09
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:57:55
	(b) (4)	

US3062157

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

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:09
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:57:55
	(b) (4)	

US3062157

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

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:09
User entered 'Clinic (Clinic)'	Colton King (b) (4)	20 Jan 2021 18:57:55
	(b) (4)	

US3062157

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

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 18:57:55

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:25:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
User entered '0'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 15:15:59
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:25:45

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:25:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	marissa Mueller (b) (4)	31 Mar 2021 15:15:59
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:25:45

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered 'Placebo (Placebo)'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered 'Placebo (Placebo)'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered 'Placebo (Placebo)'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:09:52
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:58:10
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '1'	System	20 Jan 2021 18:58:10

US3062157

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'I'	System	20 Jan 2021 18:58:10

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '164.0' cm	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '102.7' kg	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '38.18412'	System	20 Jan 2021 18:59:44
DataPoint set to visible.	System	20 Jan 2021 18:58:10

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '164.0' cm	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '102.7' kg	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '38.18412'	System	20 Jan 2021 18:59:44
DataPoint set to visible.	System	20 Jan 2021 18:58:10

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '13:23'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '19 Jan 2021 13:23'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '97.3' F	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered 'Oral (Oral)'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered empty.	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '55'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'bpm'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '16'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'breaths/min'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '138'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'mmHg'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '96'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'mmHg'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '164.0' cm	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '102.7' kg	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '38.18412'	System	20 Jan 2021 18:59:44
DataPoint set to visible.	System	20 Jan 2021 18:58:10

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '14:58'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '19 Jan 2021 14:58'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 08:46:11
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (b) (4)	marissa Mueller (b) (4)	21 Jan 2021 18:59:00
answered with 'NCS' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Jan 2021 18:59:44
User entered '96.3' F	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered 'Oral (Oral)'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered empty.	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '46'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'bpm'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '16'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'breaths/min'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '119'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'mmHg'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:10:25
User entered '68'	Colton King (b) (4)	20 Jan 2021 18:59:44
	(b) (4)	

US3062157

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'mmHg'	System	20 Jan 2021 18:59:44

US3062157

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:23
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 18:59:53
	(b) (4)	

US3062157

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:23
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 18:59:53
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered empty.	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered empty.	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'mRNA-1273'	System	20 Jan 2021 19:00:08
DataPoint set to visible.	System	20 Jan 2021 18:58:10

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered '14:26'	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '19 Jan 2021 14:26'	System	20 Jan 2021 19:00:08

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered 'Left Arm (LEFT ARM)'	Colton King (b) (4)	20 Jan 2021 19:00:08
	(b) (4)	

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:11:54
User entered 'ONCE'	System	20 Jan 2021 19:00:08

US3062157

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

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 19:00:08

US3062157

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:02
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 19:00:35
	(b) (4)	

US3062157

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:02
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 19:00:35
	(b) (4)	

US3062157

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:02
User entered '13:27'	Colton King (b) (4)	20 Jan 2021 19:00:35
	(b) (4)	

US3062157

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '19 Jan 2021 13:27'	System	20 Jan 2021 19:00:35

US3062157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:08
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 19:01:00
	(b) (4)	

US3062157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "unscheduled kit used. accession 1F623620263"; Kindly consider provide tracking number & shipped date to track the sample, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:10:01
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "unscheduled kit used. accession 1F623620263"; Kindly consider provide tracking number & shipped date to track the sample, else clarify.' answered with 'receveid results received report on 1/26/21. See Preclarus lab portal. this report has been rep-labeled as OL-1' (Site from DM).	marissa Mueller (b) (4)	05 Apr 2021 16:15:26
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "unscheduled kit used. accession 1F623620263"; Kindly consider provide tracking number & shipped date to track the sample, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 12:03:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, swab sample swab sample for 19-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 12:03:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, swab sample swab sample for 19-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' answered with ' unscheduled kit used. accession 1F623620263' (Site from DM).	marissa Mueller (b) (4)	23 Mar 2021 18:02:29

US3062157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, swab sample swab sample for 19-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 07:22:59
	(b) (4), (b) (6)	02 Mar 2021 16:12:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:30:15
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'correct as entered' (Site from DM).	Colton King (b) (4)	11 Feb 2021 17:29:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:38:54
User entered '19 Jan 2021'	Colton King (b) (4)	20 Jan 2021 19:01:00

US3062157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:08
User entered '13:24'	Colton King (b) (4)	20 Jan 2021 19:01:00
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered '19 Jan 2021 13:24'	System	20 Jan 2021 19:01:00

US3062157

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

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:12:15
User entered 'Yes (Y)'	Colton King (b) (4)	20 Jan 2021 19:01:03
	(b) (4)	

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

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:53:31
User entered 'I'	System	20 Jan 2021 19:01:03

US3062157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:14:38
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 14:32:29
	(b) (4)	

US3062157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:14:38
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 07:13:55
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct as entered, deviation routing ' (Site from System).	Riley King (b) (4)	21 Feb 2021 21:12:28
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '3 Feb 2021'	Colton King (b) (4)	17 Feb 2021 00:41:01
	(b) (4)	04 Feb 2021 14:32:29

US3062157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:14:38
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	04 Feb 2021 14:32:29
	(b) (4)	

US3062157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:14:38
User entered empty.	Colton King (b) (4)	04 Feb 2021 14:32:29
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:15:21
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 14:32:59
	(b) (4)	

US3062157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User entered 'I'	System	04 Feb 2021 14:32:59

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:39:28
User entered '1'	System	04 Feb 2021 14:32:59
DataPoint set to visible.	System	04 Feb 2021 14:32:59

US3062157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:16:41
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:14:52
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:16:41
User entered '25 Feb 2021'	Colton King (b) (4)	25 Feb 2021 22:14:52
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:16:41
User entered 'Clinic (Clinic)'	Colton King (b) (4)	25 Feb 2021 22:14:52
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'OLD29'	System	25 Feb 2021 22:14:52

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered '25 Feb 2021'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered '13:10'	Colton King (b) (4)	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered '25 Feb 2021 13:10'	System	25 Feb 2021 22:18:22

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered '98.0' F	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered 'Oral (Oral)'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered '91'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'bpm'	System	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User entered '16'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'breaths/min'	System	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Feb 2021 22:18:38
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	25 Feb 2021 22:18:38
User entered '126' reason for change: Data Entry Error	Colton King (b) (4)	25 Feb 2021 22:18:38
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Feb 2021 22:18:22
User entered '12'	Colton King (b) (4)	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'mmHg'	System	25 Feb 2021 22:18:22

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:17:01
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	25 Feb 2021 22:18:38
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 22:18:38
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	25 Feb 2021 22:18:22
User entered '91'	Colton King (b) (4)	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'mmHg'	System	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.	(b) (4)	02 Mar 2021 16:18:47
DataPoint Verified.	(b) (4)	02 Mar 2021 16:17:01
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:44
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '25 Feb 2021'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:29
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '14:43'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered '25 Feb 2021 14:43'	System	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:27
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '98.8' F	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:26
DataPoint Verified.		02 Mar 2021 16:17:01
User entered 'Oral (Oral)'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

US3062157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:23
DataPoint Verified.		02 Mar 2021 16:17:01
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:21
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '97'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'bpm'	System	25 Feb 2021 22:18:22

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:20
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '16'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'breaths/min'	System	25 Feb 2021 22:18:22

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.		02 Mar 2021 16:18:18
DataPoint Verified.		02 Mar 2021 16:17:01
User entered '126'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'mmHg'	System	25 Feb 2021 22:18:22

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:14
DataPoint Un-verified.	(b) (4)	02 Mar 2021 16:18:17
DataPoint Verified.	(b) (4)	02 Mar 2021 16:17:01
User entered '93'	Colton King (b) (4)	25 Feb 2021 22:18:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'mmHg'	System	25 Feb 2021 22:18:22

US3062157

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:49
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:19:49
	(b) (4)	

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:20:49
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	25 Feb 2021 22:19:55
User entered '25 Feb 2021' reason for change: Data Entry Error	Colton King (b) (4)	25 Feb 2021 22:19:55
	(b) (4)	
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	25 Feb 2021 22:19:49
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:19:49
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:20:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:20:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered empty.	Colton King (b) (4)	25 Feb 2021 22:20:44

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'mRNA-1273'	System	25 Feb 2021 22:20:44
DataPoint set to visible.	System	04 Feb 2021 14:32:59

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered '25 Feb 2021'	Colton King (b) (4)	25 Feb 2021 22:20:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered '14:12'	Colton King (b) (4)	25 Feb 2021 22:20:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered '25 Feb 2021 14:12'	System	25 Feb 2021 22:20:44

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered 'Left Arm (LEFT ARM)'	Colton King (b) (4)	25 Feb 2021 22:20:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:15
User entered 'ONCE'	System	25 Feb 2021 22:20:44

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 22:20:44

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:21:23
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 22:20:57

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:21:08
User entered 'I'	System	25 Feb 2021 22:20:57

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:12:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 15:32:47
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:12:57
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 09:00:01
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'protocol deviation completed' (Site from System).	Cayla Lawless (b) (4)	11 Mar 2021 18:30:46
	(b) (4)	
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Mar 2021 15:32:47
User entered '08 Mar 2021'	Janna Martinez (b) (4)	10 Mar 2021 15:32:47
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:12:57
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	10 Mar 2021 15:32:47
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:12:57
User entered empty.	Janna Martinez (b) (4)	10 Mar 2021 15:32:47
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:13:07
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 15:33:37
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:55:09
User entered 'I'	System	10 Mar 2021 15:33:37

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:20:43
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 13:32:23
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:20:43
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1 Apr 2021'	Colton King (b) (4)	05 Apr 2021 13:32:23
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:20:43
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Colton King (b) (4)	05 Apr 2021 13:32:23
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 13:32:23

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1 Apr 2021'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '14:30'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 14:30'	System	05 Apr 2021 13:34:08

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '98.0' F	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '91'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 13:34:08

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '17'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 13:34:08

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '112'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:34:08

US3062157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:04
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '78'	Colton King (b) (4)	05 Apr 2021 13:34:08
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:34:08

US3062157

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:13
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	05 Apr 2021 13:34:33
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:13
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Colton King (b) (4)	05 Apr 2021 13:34:33
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:25
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 13:35:09
	(b) (4)	

US3062157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:25
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1 Apr 2021'	Colton King (b) (4)	05 Apr 2021 13:35:09
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:21:25
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '14:39'	Colton King (b) (4)	05 Apr 2021 13:35:09
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 14:39'	System	05 Apr 2021 13:35:09

US3062157

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:06:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:09:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	29 Mar 2021 19:12:36
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 14:27:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:34:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	30 Mar 2021 16:46:57

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:16:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:16:08
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 19:15:54
User entered 'worsening osteoarthritis bilateral knees'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Yes (Y)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'No (N)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'No (N)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: please clarify event start date, as results of CT scan on 27 Jan 2021 were "worsening OA bilateral knees"' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:00:01
	(b) (4), (b) (6)	29 Apr 2021 17:31:43
Query 'PV Query: please clarify event start date, as results of CT scan on 27 Jan 2021 were "worsening OA bilateral knees"' answered with 'reconciled ' (Site from Safety). DataPoint Un-verified.	Riley King (b) (4)	27 Apr 2021 18:03:30
	(b) (4)	
	Riley King (b) (4)	27 Apr 2021 18:02:58
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	27 Apr 2021 18:02:58
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	27 Apr 2021 18:02:58
	(b) (4)	
User opened query 'PV Query: please clarify event start date, as results of CT scan on 27 Jan 2021 were "worsening OA bilateral knees"' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	27 Apr 2021 14:48:25
	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:43:22
User closed query 'please verify end date (date of surgery) for knee replacement' (Site from CRA).		12 Apr 2021 20:43:20
DataPoint Un-verified.		12 Apr 2021 20:43:14
DataPoint Verified.		12 Apr 2021 20:28:26
Signature has been broken.	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
Query 'please verify end date (date of surgery) for knee replacement' answered with 'pending records' (Site from CRA).	marissa Mueller (b) (4)	07 Apr 2021 15:48:14
	(b) (4)	
User opened query 'please verify end date (date of surgery) for knee replacement' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:05:18
DataPoint Un-verified.		07 Apr 2021 14:04:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Yes (Y)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
Signature has been broken.	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
User entered '27 Mar 2021' reason for change: New Information	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:12:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:48:43
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 14:04:51
	(b) (4), (b) (6)	06 Apr 2021 13:55:08
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:15:16

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Yes (Y)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide hospital admission and discharge dates.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:12:19
Query 'PV Query: Please provide hospital admission and discharge dates.' answered with 'Admission date present, pending records for discharge date ' (Site from Safety).	Riley King (b) (4)	06 Apr 2021 18:04:28
User opened query 'PV Query: Please provide hospital admission and discharge dates.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide hospital admission and discharge dates.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:56:11
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)	01 Apr 2021 09:23:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
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 'Admission date is recorded, and subject was not admitted to ICU. Unknown discharge date at this time, will update when medical records arrive. ' (Site from System).	Riley King (b) (4)	29 Mar 2021 19:16:52
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	29 Mar 2021 19:15:16
User entered 'I'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '11 Feb 2021'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:40:09
User closed query 'PV Query: Please provide hospital admission and discharge dates. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:34:31
Query 'PV Query: Please provide hospital admission and discharge dates. ' answered with 'updated ' (Site from Safety).	marissa Mueller (b) (4)	13 Apr 2021 13:15:29
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	13 Apr 2021 13:15:14
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	13 Apr 2021 13:15:14
	(b) (4)	
User entered '27 Mar 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	13 Apr 2021 13:15:14
	(b) (4)	
User opened query 'PV Query: Please provide hospital admission and discharge dates. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:13:26
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'No (N)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User closed query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment medication before and after event start date, please update action taken with study drug accordingly.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:55:45
Query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment medication before and after event start date, please update action taken with study drug accordingly.' answered with 'reconciled' (Site from Safety).	Riley King (b) (4)	06 Apr 2021 18:04:44
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	06 Apr 2021 18:02:49
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	06 Apr 2021 18:02:49
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Riley King (b) (4)	06 Apr 2021 18:02:49
	(b) (4)	
User opened query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment medication before and after event start date, please update action taken with study drug accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:56:31
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'I'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'I'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
DataPoint Un-verified.	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
Signature has been broken.	(b) (4)	
	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sherry Henning (b) (4)	12 Apr 2021 19:35:22
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:56:09
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:49:03
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:55:28
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: please provide results of CT scans to Safety_Moderna@iqvia.com or fax to 866.599.1342. thank you!' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:00:14
Query 'PV Query: please provide results of CT scans to Safety_Moderna@iqvia.com or fax to 866.599.1342. thank you!' answered with 'this has been faxed ' (Site from Safety).	Riley King (b) (4) (b) (4)	27 Apr 2021 18:46:15
User opened query 'PV Query: please provide results of CT scans to Safety_Moderna@iqvia.com or fax to 866.599.1342. thank you!' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:48:35
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
User closed query 'PV Query: Please provide results of CT scans from 27 Jan 2021 if available.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:47:20
User closed query 'PV Query: Please confirm if subject was hospitalized starting on 11 Feb 2021 through 27 Mar 2021 for entire duration. If subject was discharged and re-admitted during that timeframe, please provide all discharge and admission dates in narrative.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:47:17
User closed query 'PV Query: Clarifying testosterone start date query per request. As event start date is reported as 11 Feb 2021, determining the specific date when the subject began taking testosterone, will determine if it is recorded as a concomitant medication. Only the month is reported (Feb), so providing the specific day of the month will determine its status as a concomitant medication.' (Site from Safety).		20 Apr 2021 15:47:14
DataPoint Verified.		20 Apr 2021 15:36:05
Query 'PV Query: Please provide results of CT scans from 27 Jan 2021 if available.' answered with 'The results were worsening OA bilateral knees. I can provide results if you provide fax number for me to send. ' (Site from Safety).	Riley King (b) (4) (b) (4)	19 Apr 2021 18:18:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Clarifying testosterone start date query per request. As event start date is reported as 11 Feb 2021, determining the specific date when the subject began taking testosterone, will determine if it is recorded as a concomitant medication. Only the month is reported (Feb), so providing the specific day of the month will determine its status as a concomitant medication.' answered with 'This medication was started in February 2020, not 2021. Subject was taking this medication prior to study start and he continues to take it now. ' (Site from Safety).	Riley King (b) (4)	19 Apr 2021 18:16:38
Query 'PV Query: Please confirm if subject was hospitalized starting on 11 Feb 2021 through 27 Mar 2021 for entire duration. If subject was discharged and re-admitted during that timeframe, please provide all discharge and admission dates in narrative.' answered with 'reconciled' (Site from Safety).	Riley King (b) (4)	19 Apr 2021 18:09:46
DataPoint Un-verified.	Riley King (b) (4)	19 Apr 2021 18:09:28
Signature has been broken.	Riley King (b) (4)	19 Apr 2021 18:09:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE THAT HE HAD BILATERAL KNEE REPLACEMENTS, THE FIRST ONE ON 2/11/2021, subject was admitted from 2/11/2021 to 2/13/2021. THE SECOND ONE ON 3/25/2021. Subject was admitted from 3/25/2021 until 3/27/2021 SUBJECT IN OFFICE AT 3/29/2021 AND SIGNED RELEASE OF RECORDS. FAXED TO SURGERY CENTER FOR RECORDS. 4/9/2021 RECEIVED MEDICAL RECORDS ON 4/8/2021, SUBJECT HAD LEFT TOTAL KNEE REPLACEMENT ON 2/11/21 AND RIGHT TOTAL KNEE REPLACEMENT ON 3/25/2021. FOLLOWING BOTH PROCEDURES SUBJECT HAD AES, AND MEDICATIONS TO HELP WITH POST OPERATIVE AES. SUBJECT HAD PAIN PRIOR TO AND FOLLOWING PROCEDURES, NSAIDS AND NARCOTIC PAIN MEDICATION ORDERED FOR PAIN CONTROL. ON 1/27/2021 SUBJECT HAD CT BILATERAL KNEES WITHOUT CONTRACT. SUBJECT WAS NOT TESTED FOR COVID WHILE ADMITTED, SUBJECT WAS ORDERED MEDICATIONS FOR THREE HEALTH HISTORY TERMS, THESE DID NOT WORSEN IN THE HOSPITAL, BUT MEDS WERE ORDERED AND ADMINISTERED. ALL NEW AND UPDATED MEDICATIONS, AES, AND PROCEDURES HAVE BEEN UPDATED IN SOURCE AND EDC.' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	19 Apr 2021 18:09:28
User opened query 'PV Query: Clarifying testosterone start date query per request. As event start date is reported as 11 Feb 2021, determining the specific date when the subject began taking testosterone, will determine if it is recorded as a concomitant medication. Only the month is reported (Feb), so providing the specific day of the month will determine its status as a concomitant medication.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:47:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if subject was hospitalized starting on 11 Feb 2021 through 27 Mar 2021 for entire duration. If subject was discharged and re-admitted during that timeframe, please provide all discharge and admission dates in narrative.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:47:02
User opened query 'PV Query: Please provide results of CT scans from 27 Jan 2021 if available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:46:27
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
User closed query 'PV Query: Please confirm start date for testosterone. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:34:33
Query 'PV Query: Please confirm start date for testosterone. ' answered with 'please, clarify. Subject reports testosterone cypionate Q2 weeks beginning in 2/2020 as reported in form. ' (Site from Safety).	marissa Mueller (b) (4)	13 Apr 2021 13:18:53
User opened query 'PV Query: Please confirm start date for testosterone. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
DataPoint Un-verified.	Riley King (b) (4)	09 Apr 2021 14:26:17
Signature has been broken.	Riley King (b) (4)	09 Apr 2021 14:26:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE THAT HE HAD BILATERAL KNEE REPLACEMENTS, THE FIRST ONE ON 2/11/2021 AND THE SECOND ONE ON 3/25/2021. SUBJECT IN OFFICE AT 3/29/2021 AND SIGNED RELEASE OF RECORDS. FAXED TO SURGERY CENTER FOR RECORDS. 4/9/2021 Received medical records on 4/8/2021, subject had left total knee replacement on 2/11/21 and right total knee replacement on 3/25/2021. Following both procedures subject had AEs, and medications to help with post operative AEs. Subject had pain prior to and following procedures, NSAIDs and narcotic pain medication ordered for pain control. On 1/27/2021 subject had CT bilateral knees without contract. Subject was not tested for COVID while admitted, subject was ordered medications for three health history terms, these did not worsen in the hospital, but meds were ordered and administered. All new and updated medications, AEs, and procedures have been updated in source and EDC.' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	09 Apr 2021 14:26:17
User closed query 'PV Query: Please specify which knees were replaced on their respective dates.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:56:50
User closed query 'PV Query: Please confirm start date for testosterone.' (Site from Safety).		07 Apr 2021 16:56:42
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).		07 Apr 2021 16:56:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given, in addition to replacement surgeries, for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:56:29
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).		07 Apr 2021 16:56:18
Query 'PV Query: Please specify which knees were replaced on their respective dates.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:50:29
Query 'PV Query: Please confirm start date for testosterone.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:50:15
Query 'PV Query: Please provide treatment given, in addition to replacement surgeries, for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:49:58
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 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:49:43
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 'pending records' (Site from Safety).	marissa Mueller (b) (4)	07 Apr 2021 15:49:23

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please specify which knees were replaced on their respective dates.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:57:17
User opened query 'PV Query: Please confirm start date for testosterone.' (Site from Safety).		06 Apr 2021 13:57:07
User opened query 'PV Query: Please provide treatment given, in addition to replacement surgeries, 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).		06 Apr 2021 13:55:36
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).		06 Apr 2021 13:55:17
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).		06 Apr 2021 13:53:45
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:08
User entered 'Subject notified site that he had bilateral knee replacements, the first one on 2/11/2021 and the second one on 3/25/2021. Subject in office at 3/29/2021 and signed release of records. Faxed to surgery center for records.'	Riley King (b) (4)	29 Mar 2021 19:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 19:15:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Procedural nausea, LLT: Postoperative nausea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:31:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:07:41
User entered 'post operative nausea'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:07:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User entered empty.	System	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User entered empty.	System	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:07:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[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 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User entered '0'	System	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47
User entered 'I'	System	09 Apr 2021 14:07:13

US3062157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:47

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural constipation, LLT: Postoperative constipation - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 14:08:58
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 14:08:58
Data point term sent to Coder	System	12 Apr 2021 13:57:30
User closed query 'DM-Coding: The verbatim cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	12 Apr 2021 13:57:26
Query 'DM-Coding: The verbatim cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	12 Apr 2021 13:57:26
User entered 'POST OPERATIVE constipation' reason for change: Data Entry Error	(b) (4)	
User opened query 'DM-Coding: The verbatim cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	marissa Mueller (b) (4)	12 Apr 2021 13:57:07
	(b) (4)	
	Coder Import (b) (4)	12 Apr 2021 10:16:54
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:08:45
User entered 'post operative'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User entered empty.	System	09 Apr 2021 14:08:19

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:08:19

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User entered empty.	System	09 Apr 2021 14:08:19

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:08:19

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:19

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[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 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User entered '0'	System	09 Apr 2021 14:08:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49
User entered 'I'	System	09 Apr 2021 14:08:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
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.	Coder Import (b) (4)	09 Apr 2021 14:32:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:32:29
Data point term sent to Coder	System	09 Apr 2021 14:09:48
User entered 'muscle spasms, generalized'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User entered empty.	System	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User entered empty.	System	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

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 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:08:56
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User entered '0'	System	09 Apr 2021 14:08:56

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06
User entered 'I'	System	09 Apr 2021 14:08:56

US3062157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:06

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
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)	09 Apr 2021 14:32:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:32:26
Data point term sent to Coder	System	09 Apr 2021 14:09:47
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User entered empty.	System	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User entered empty.	System	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

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 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:29
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User entered '0'	System	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42
User entered 'I'	System	09 Apr 2021 14:09:29

US3062157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:42

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
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: Post procedural pruritus, LLT: Post procedural pruritus - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 10:15:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 10:15:59
Data point term sent to Coder	System	09 Apr 2021 14:10:48
User entered 'post operative itching'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User entered empty.	System	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User entered empty.	System	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[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 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:09:57
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User entered '0'	System	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48
User entered 'I'	System	09 Apr 2021 14:09:57

US3062157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:48

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:33:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:33:25
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:11:52
User entered 'anxiety'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:10:52

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:10:52

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:10:52
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:10:52

US3062157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:10:52

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Procedural nausea, LLT: Postoperative nausea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:33:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:33:24
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:11:56
User entered 'post operative nausea'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:11:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:11:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:11:25
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:11:25

US3062157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:11:25

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural constipation, LLT: Postoperative constipation - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 14:51:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 14:51:20
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:12:57
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:12:04

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:12:04

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:04
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:12:04

US3062157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:12:04

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
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.	Coder Import (b) (4)	09 Apr 2021 14:33:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:33:46
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:12:58
User entered 'muscle spasms, generalized'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:12:47

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:12:47

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:12:47
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:12:47

US3062157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:12:47

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: 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)	09 Apr 2021 14:34:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:34:02
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:13:59
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:13:23

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:13:23

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:23
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:13:23

US3062157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:13:23

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural pruritus, LLT: Post procedural pruritus - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 10:15:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 10:15:59
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 14:14:00
User entered 'post operative itching'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:13:55

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:13:55

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:13:55
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:13:55

US3062157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:13:55

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	09 Apr 2021 14:14:18

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 20:52:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 20:52:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:28:26
Data point term sent to Coder	System	12 Apr 2021 19:32:54
User entered 'obesity'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '11 Feb 2021'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:32:50
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	09 Apr 2021 14:14:18

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:32:50
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	09 Apr 2021 14:14:18

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'I'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:32:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 19:32:50
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	09 Apr 2021 14:14:18

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 19:32:50
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	09 Apr 2021 14:14:18

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	12 Apr 2021 19:19:39
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	09 Apr 2021 14:14:18

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:22:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:22:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:28:26
Data point term sent to Coder	System	12 Apr 2021 20:10:47
User entered 'gastroesophageal reflux disease'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:10:28

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:10:28

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:10:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:10:28

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:10:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:22:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
Data point term sent to Coder	System	12 Apr 2021 20:15:54
User entered 'obstructive sleep apnea'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '11 Feb 2021'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:14:54

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Yes (Y)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:06:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:14:54

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered 'I'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:15:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:15:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sherry Henning (b) (4)	12 Apr 2021 20:15:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:14:54
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:28:26
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 20:14:54
	(b) (4)	

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:14:54

US3062157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:06:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:14:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:06:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:22:59
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:27:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 13:13:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 13:13:31
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:29:38
User entered 'elaquis'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'atrial fibrillation'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:58:50
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '2.5'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:59:00
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'twice daily (BID)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:58:55
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:59:27
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:09:55
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:04
answered with '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	09 Aug 2020 21:28:43
User entered 'un Mar 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 14:59:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:28:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Aug 2020 21:28:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:28:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:28:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:30:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:30:39
Data point term sent to Coder	System	09 Aug 2020 21:29:39
User entered 'loratadine'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'seasonal allergies'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '10'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES (JAN2012). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:36:03
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES (JAN2012). Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	09 Sep 2020 23:41:46
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES (JAN2012). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 15:42:02
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).	(b) (4), (b) (6)	11 Aug 2020 11:10:04
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.' answered with 'correct as entered' (Site from System).	Sherry Henning (b) (4)	09 Aug 2020 22:09:20
	(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	09 Aug 2020 21:29:22
User entered 'un Jan 2010'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:29:22
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:29:22

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:29:22

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:29:22

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:38:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:38:21
Data point term sent to Coder	System	09 Aug 2020 21:30:39
User entered 'Clobetasol 0.5%'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:30:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'eczema, generalized'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'I'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Other (OTHER)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'application'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Topical (TOPICAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:10:14
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:26
answered with '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	09 Aug 2020 21:30:26
User entered 'un Jan 2015'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:30:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:30:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:30:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:30:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 21:36:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 21:36:34
Data point term sent to Coder	System	09 Aug 2020 21:35:40
User entered 'fenofibrate'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:35:30

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'hypercholesterolemia'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '160'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'once daily (QD)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:10:37
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:33
answered with '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	09 Aug 2020 21:35:30
User entered 'un Jan 2016'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:35:30
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:35:30

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:35:30

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:35:30

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:09:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:09:18
Data point term sent to Coder	System	09 Aug 2020 21:36:40
User entered 'sotalol'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:36:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'atrial fibrillation'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '120'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'twice daily (BID)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:10:43
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:39
answered with '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	09 Aug 2020 21:36:26
User entered 'un Jan 2015'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:36:26
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Aug 2020 21:36:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:36:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:36:26

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:39:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:39:35
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:38:42
User entered 'testosterone cypionate'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'low testosterone level'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '100'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'other (OTHER)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'every two weeks'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:10:56
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:46
answered with '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	09 Aug 2020 21:37:57
User entered 'un Feb 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:37:57
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:37:57

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:37:57

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:37:57

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 00:48:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 00:48:17
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:39:43
User entered 'hydrocodone 7.5mg/acetaminophen 325mg'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'chronic back pain'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'I'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'tablet (TABLET)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:11:06
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:09:52
answered with '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	09 Aug 2020 21:39:07
User entered 'un Jan 2012'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:07
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:39:07

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:39:07

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:39:07

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 21:41:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 21:41:35
Data point term sent to Coder	System	09 Aug 2020 21:40:43
User entered 'citalopram'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:39:47

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'depression'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '40'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'once daily (QD)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:11:18
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:10:00
answered with '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	09 Aug 2020 21:39:47
User entered 'un Jan 2014'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:39:47
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:39:47

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:39:47

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:39:47

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:42:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 21:42:35
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:41:44
User entered 'cyclobenzaprine'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'chronic back pain'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '10'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:11:25
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:10:07
answered with '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	09 Aug 2020 21:40:52
User entered 'un Jan 2019'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:40:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:40:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:40:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 21:40:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 07:19:24
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 07:19:24
Data point term sent to Coder	System	09 Aug 2020 21:41:45
User entered 'celebrex'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 21:41:40

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'osteoarthritis, bilateral knees'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:36:26
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	09 Sep 2020 23:42:08
	(b) (4)	
User entered '200' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Sep 2020 23:42:04
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 15:43:15
User entered '20'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'once daily (QD)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
	(b) (4), (b) (6)	11 Aug 2020 11:11:35
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.'	Sherry Henning (b) (4)	09 Aug 2020 22:10:19
answered with '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	09 Aug 2020 21:41:40
User entered 'un Jun 2019'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:41:40
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:41:40

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:41:40

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:41:40

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:28:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:28:11
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 21:43:45
User entered 'fluconazole'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'nail fungus, bilateral feet'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '150'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'once daily (QD)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '6 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Sherry Henning (b) (4)	09 Aug 2020 21:42:55
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:42:55

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 21:42:55

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 21:42:55

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
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: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 12:03:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 12:03:39
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
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: GLUCOCORTICOIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 12:24:51
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 12:24:51
Data point term sent to Coder	System	04 Sep 2020 21:51:34
User entered 'cortisone injection'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'OSTEOARTHRITIS, BILATERAL KNEES'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '300'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'mg (mg)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	04 Sep 2020 21:52:32
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	04 Sep 2020 21:52:32
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	04 Sep 2020 21:51:33
User entered 'once (ONCE)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'Other (OTHER)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'INTRARTICULAR'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '28 Aug 2020'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered '0'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	04 Sep 2020 21:52:32
User entered '28 Aug 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 21:52:32
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	04 Sep 2020 21:51:33
User entered '28 Aug 2002'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:26:10
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 21:51:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User entered empty.	System	04 Sep 2020 21:51:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User entered empty.	System	04 Sep 2020 21:51:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:55
User entered empty.	System	04 Sep 2020 21:51:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:53:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:53:41
Data point term sent to Coder	System	10 Nov 2020 00:52:32
User entered 'Influenza vaccine'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'influenza prophylaxis'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered '0.5'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'mL (mL)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered empty.	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'once (ONCE)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered empty.	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered empty.	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered '14 Oct 2020'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered '0'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'No (N)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered '14 Oct 2020'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:16:58
User entered 'No (N)'	Sherry Henning (b) (4)	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User entered empty.	System	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User entered empty.	System	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:42:53
User entered empty.	System	10 Nov 2020 00:51:54

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
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.	(b) (4) Coder Import (b) (4)	09 Apr 2021 12:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 12:47:40
Data point term sent to Coder	System	09 Apr 2021 12:46:22
User entered 'Tylenol'	Riley King (b) (4)	09 Apr 2021 12:46:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User entered 'Post operative pain'	(b) (4) Riley King (b) (4) (b) (4)	09 Apr 2021 12:46:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1000'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:46:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
User entered empty.	System	09 Apr 2021 12:46:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
User entered empty.	System	09 Apr 2021 12:46:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:45:03
User entered empty.	System	09 Apr 2021 12:46:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:22:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:48:32
User entered 'dexamethasone'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:47:34

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '10'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:47:34
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
User entered empty.	System	09 Apr 2021 12:47:34

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
User entered empty.	System	09 Apr 2021 12:47:34

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:49:32
User entered empty.	System	09 Apr 2021 12:47:34

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:29:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:29:44
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder User entered 'meloxicam'	System Riley King (b) (4) (b) (4)	09 Apr 2021 12:48:32 09 Apr 2021 12:48:11

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '15'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:11
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
User entered empty.	System	09 Apr 2021 12:48:11

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
User entered empty.	System	09 Apr 2021 12:48:11

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:06
User entered empty.	System	09 Apr 2021 12:48:11

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:45
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:49:33
User entered 'midazolam'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:48:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '2'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:48:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
User entered empty.	System	09 Apr 2021 12:48:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
User entered empty.	System	09 Apr 2021 12:48:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:30
User entered empty.	System	09 Apr 2021 12:48:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:50:35
User entered 'famotidine'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:49:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '20'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:49:43
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
User entered empty.	System	09 Apr 2021 12:49:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
User entered empty.	System	09 Apr 2021 12:49:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:50:51
User entered empty.	System	09 Apr 2021 12:49:43

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:23:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:23:44
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:51:37
User entered 'hydromorphone'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:50:50

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:50:50
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
User entered empty.	System	09 Apr 2021 12:50:50

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
User entered empty.	System	09 Apr 2021 12:50:50

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:21
User entered empty.	System	09 Apr 2021 12:50:50

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:52:38
User entered 'fentanyl'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:52:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '100'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'ug (ug)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
User entered empty.	System	09 Apr 2021 12:52:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
User entered empty.	System	09 Apr 2021 12:52:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:51:45
User entered empty.	System	09 Apr 2021 12:52:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 12:54:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 12:54:33
Data point term sent to Coder	System	09 Apr 2021 12:53:39
User entered 'tramadol'	Riley King (b) (4)	09 Apr 2021 12:52:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '50'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'four times daily (QID)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:52:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
User entered '4'	System	09 Apr 2021 12:52:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
User entered '1'	System	09 Apr 2021 12:52:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:12
User entered '804 (804)'	System	09 Apr 2021 12:52:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 12:55:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 12:55:41
Data point term sent to Coder	System	09 Apr 2021 12:54:40
User entered 'omeprazole'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:53:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'GERD'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '20'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:53:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered '2'	System	09 Apr 2021 12:53:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered '1'	System	09 Apr 2021 12:53:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered '804 (804)'	System	09 Apr 2021 12:53:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:55:42
User entered 'milk of magnesia'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:54:45

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '30'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:54:45
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
User entered empty.	System	09 Apr 2021 12:54:45

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
User entered empty.	System	09 Apr 2021 12:54:45

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:52
User entered empty.	System	09 Apr 2021 12:54:45

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:44
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:56:42
User entered 'metoclopramide'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:55:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'GERD'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '10'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:55:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
User entered empty.	System	09 Apr 2021 12:55:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
User entered empty.	System	09 Apr 2021 12:55:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:17
User entered empty.	System	09 Apr 2021 12:55:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:31:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:31:43
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:56:43
User entered 'ondansetron'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:56:39

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative nausea'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '4'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:56:39
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	09 Apr 2021 12:56:39

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	09 Apr 2021 12:56:39

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	09 Apr 2021 12:56:39

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:59:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:59:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:34:09
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:34:09
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:33:41
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:33:41
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:58:00
User entered 'Saline flush'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:57:19

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '3'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:57:19
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
User entered '2'	System	09 Apr 2021 12:57:19

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
User entered '1'	System	09 Apr 2021 12:57:19

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:37
User entered '804 (804)'	System	09 Apr 2021 12:57:19

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 12:59:00
User entered 'Docusate sodium'	Riley King (b) (4) (b) (4)	09 Apr 2021 12:58:03

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '100'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:58:03
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered '2'	System	09 Apr 2021 12:58:03

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered '1'	System	09 Apr 2021 12:58:03

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered '804 (804)'	System	09 Apr 2021 12:58:03

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:02:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:02:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
Data point term sent to Coder	System	12 Apr 2021 19:40:09
Coding entries removed.	Sherry Henning (b) (4)	12 Apr 2021 19:39:55
	(b) (4)	
Signature has been broken.	Sherry Henning (b) (4)	12 Apr 2021 19:39:55
	(b) (4)	
User entered 'CYCLOBENZaprine' reason for change: Data Entry Error	Sherry Henning (b) (4)	12 Apr 2021 19:39:55
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:18:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:18:57
	(b) (4)	
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:00:01
User entered 'cyclobenz'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'muscle spasms, generalized'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '10'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 12:59:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
User entered empty.	System	09 Apr 2021 12:59:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
User entered empty.	System	09 Apr 2021 12:59:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:49
User entered empty.	System	09 Apr 2021 12:59:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:25:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:25:37
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:01:02
User entered 'ketorolac'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:00:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '15'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:00:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
User entered empty.	System	09 Apr 2021 13:00:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
User entered empty.	System	09 Apr 2021 13:00:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:09
User entered empty.	System	09 Apr 2021 13:00:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:21:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:21:42
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:02:03
User entered 'cefazolin'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:01:04

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'infection prophylaxis'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '2'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'g (g)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'four times daily (QID)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:15
User closed query 'please verify as 12Feb21 per CM log' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:08:58
Query 'please verify as 12Feb21 per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 20:55:27
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	12 Apr 2021 20:55:13
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	12 Apr 2021 20:55:13
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User opened query 'please verify as 12Feb21 per CM log' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:38:07
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:01:04
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
User entered '4'	System	09 Apr 2021 13:01:04

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
User entered '1'	System	09 Apr 2021 13:01:04

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:30
User entered '804 (804)'	System	09 Apr 2021 13:01:04

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 13:02:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:02:36
Data point term sent to Coder	System	09 Apr 2021 13:02:03
User entered 'Eliquis'	Riley King (b) (4)	09 Apr 2021 13:01:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'atrial fibrillation'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '5'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '12 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:01:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
User entered '2'	System	09 Apr 2021 13:01:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
User entered '1'	System	09 Apr 2021 13:01:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:47
User entered '804 (804)'	System	09 Apr 2021 13:01:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:46
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:04:05
User entered 'diphenhydramine'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:03:32

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative itching'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:03:32
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
User entered empty.	System	09 Apr 2021 13:03:32

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
User entered empty.	System	09 Apr 2021 13:03:32

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:05
User entered empty.	System	09 Apr 2021 13:03:32

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:32:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:32:37
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:07:16
User entered 'Percocet(10/325)'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:06:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '2'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'tablet (TABLET)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:06:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
User entered empty.	System	09 Apr 2021 13:06:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
User entered empty.	System	09 Apr 2021 13:06:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:02
User entered empty.	System	09 Apr 2021 13:06:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:27:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:27:25
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:08:18
User entered 'Bisacodyl suppository'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:07:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '10'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Rectal (RECTAL)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '12 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '12 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:07:46
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
User entered empty.	System	09 Apr 2021 13:07:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
User entered empty.	System	09 Apr 2021 13:07:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:18
User entered empty.	System	09 Apr 2021 13:07:46

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
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)	09 Apr 2021 13:10:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:10:43
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:09:18
User entered 'lactated ringers'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1000'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'other (OTHER)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'continuous'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:08:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
User entered empty.	System	09 Apr 2021 13:08:28

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
User entered empty.	System	09 Apr 2021 13:08:28

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:09:40
User entered empty.	System	09 Apr 2021 13:08:28

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
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 17:49:57
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 17:49:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:30:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:47
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:10:19
User entered 'normal saline'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:09:24

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1000'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'other (OTHER)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '75ml/hr'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '13 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:09:24
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
User entered empty.	System	09 Apr 2021 13:09:24

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
User entered empty.	System	09 Apr 2021 13:09:24

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:36
User entered empty.	System	09 Apr 2021 13:09:24

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:15:57
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:31:09
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 Apr 2021 19:31:09
Data point term sent to Coder Coding entries removed.	System marissa Mueller (b) (4) (b) (4)	12 Apr 2021 21:32:12 12 Apr 2021 21:31:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:37
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:11:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Marcaine 0.25%'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:10:28

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '30'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:11:41
User closed query 'Marcaine is local anesthetic, thus given sub-cutaneous' (Site from CRA).		12 Apr 2021 23:11:28
Query 'Marcaine is local anesthetic, thus given sub-cutaneous' answered with 'udpated' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 21:31:45
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	12 Apr 2021 21:31:17
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	marissa Mueller (b) (4)	12 Apr 2021 21:31:17
	(b) (4)	
User opened query 'Marcaine is local anesthetic, thus given sub-cutaneous' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:11:25
User closed query 'please verify as subcutaneous per source' (Site from CRA).		12 Apr 2021 21:11:25
Query 'please verify as subcutaneous per source' answered with 'pg 6 of conmeds states IM' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 21:07:56
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:39
DataPoint Verified.		12 Apr 2021 20:40:29
User opened query 'please verify as subcutaneous per source' (Site from CRA).		12 Apr 2021 20:36:13
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '11 Feb 2021'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
User entered empty.	System	09 Apr 2021 13:10:28

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
User entered empty.	System	09 Apr 2021 13:10:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:10:57
User entered empty.	System	09 Apr 2021 13:10:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:15:57
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:31:09
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 Apr 2021 19:31:09
Data point term sent to Coder Coding entries removed.	System marissa Mueller (b) (4) (b) (4)	12 Apr 2021 21:33:23 12 Apr 2021 21:32:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:37
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:11:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Marcaine 0.25%'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:11:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '30'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:13:02
User closed query 'please verify as subcutaneous per source (marcaine is local anesthetic)' (Site from CRA).		12 Apr 2021 23:12:48
Query 'please verify as subcutaneous per source (marcaine is local anesthetic)' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 21:32:42
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	12 Apr 2021 21:32:18
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	marissa Mueller (b) (4)	12 Apr 2021 21:32:18
	(b) (4)	
User opened query 'please verify as subcutaneous per source (marcaine is local anesthetic)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:30:19
Query 'please verify as subcutaneous per source' canceled (Site from CRA).		12 Apr 2021 21:29:40
User opened query 'please verify as subcutaneous per source' (Site from CRA).		12 Apr 2021 21:12:07
User closed query 'please verify as subcutaneous per source' (Site from CRA).		12 Apr 2021 21:12:07
Query 'please verify as subcutaneous per source' answered with 'pg 6 of conmeds states Im' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 21:09:00
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:51
DataPoint Verified.		12 Apr 2021 20:40:29
User opened query 'please verify as subcutaneous per source' (Site from CRA).		12 Apr 2021 20:35:50
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
User entered empty.	System	09 Apr 2021 13:11:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
User entered empty.	System	09 Apr 2021 13:11:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:01
User entered empty.	System	09 Apr 2021 13:11:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
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.	(b) (4) Coder Import (b) (4)	09 Apr 2021 13:17:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:17:07
Data point term sent to Coder	System	09 Apr 2021 13:12:23
User entered 'Tylenol'	Riley King (b) (4)	09 Apr 2021 13:11:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '1000'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:11:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
User entered empty.	System	09 Apr 2021 13:11:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
User entered empty.	System	09 Apr 2021 13:11:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:19
User entered empty.	System	09 Apr 2021 13:11:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:22:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:22:45
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:29
Data point term sent to Coder	System	09 Apr 2021 13:15:26
User entered 'dexamethasone'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:14:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '10'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:14:52
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
User entered empty.	System	09 Apr 2021 13:14:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
User entered empty.	System	09 Apr 2021 13:14:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:40
User entered empty.	System	09 Apr 2021 13:14:52

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:44
Data point term sent to Coder	System	09 Apr 2021 13:23:42
User entered 'meloxicam'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '15'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:23:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User entered empty.	System	09 Apr 2021 13:23:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User entered empty.	System	09 Apr 2021 13:23:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:51
User entered empty.	System	09 Apr 2021 13:23:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:30:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:30:46
Data point term sent to Coder	System	09 Apr 2021 13:24:42
User entered 'midazolam'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '2'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User entered empty.	System	09 Apr 2021 13:24:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User entered empty.	System	09 Apr 2021 13:24:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:04:38
User entered empty.	System	09 Apr 2021 13:24:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:25:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:25:37
Data point term sent to Coder	System	09 Apr 2021 13:24:43
User entered 'hydromorphone'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0.5'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:24:41
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User entered empty.	System	09 Apr 2021 13:24:41

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User entered empty.	System	09 Apr 2021 13:24:41

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:05
User entered empty.	System	09 Apr 2021 13:24:41

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:32:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:32:37
Data point term sent to Coder	System	09 Apr 2021 13:25:44
User entered 'Percocet(10/325)'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:25:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '2'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'tablet (TABLET)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:25:42
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User entered empty.	System	09 Apr 2021 13:25:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User entered empty.	System	09 Apr 2021 13:25:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:25
User entered empty.	System	09 Apr 2021 13:25:42

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
Data point term sent to Coder	System	09 Apr 2021 13:28:49
User entered 'diphenhydramine'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative itching'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:28:18
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User entered empty.	System	09 Apr 2021 13:28:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User entered empty.	System	09 Apr 2021 13:28:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:44
User entered empty.	System	09 Apr 2021 13:28:18

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:43
Data point term sent to Coder	System	09 Apr 2021 13:29:51
User entered 'ondansetron'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative nausea'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '4'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:29:02
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User entered empty.	System	09 Apr 2021 13:29:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User entered empty.	System	09 Apr 2021 13:29:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:02:54
User entered empty.	System	09 Apr 2021 13:29:02

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:44
Data point term sent to Coder	System	09 Apr 2021 13:30:52
User entered 'metoclopramide'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'GERD'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '10'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:05
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User entered empty.	System	09 Apr 2021 13:30:05

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User entered empty.	System	09 Apr 2021 13:30:05

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:54
User entered empty.	System	09 Apr 2021 13:30:05

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:31:44
Data point term sent to Coder	System	09 Apr 2021 13:30:52
User entered 'oxycontin'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '10'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:30:44
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User entered '2'	System	09 Apr 2021 13:30:44

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User entered '1'	System	09 Apr 2021 13:30:44

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:38
User entered '804 (804)'	System	09 Apr 2021 13:30:44

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:32:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:32:37
Data point term sent to Coder	System	09 Apr 2021 13:31:53
User entered 'tramadol'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '50'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'four times daily (QID)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:31:23
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User entered '4'	System	09 Apr 2021 13:31:23

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User entered '1'	System	09 Apr 2021 13:31:23

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:57:06
User entered '804 (804)'	System	09 Apr 2021 13:31:23

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:33:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:33:41
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:32:54
User entered 'Tylenol'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '650'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:15
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User entered empty.	System	09 Apr 2021 13:32:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User entered empty.	System	09 Apr 2021 13:32:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:37
User entered empty.	System	09 Apr 2021 13:32:15

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:33:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:33:41
Data point term sent to Coder	System	09 Apr 2021 13:32:54
User entered 'omeprazole'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'GERD'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '20'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:32:53
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '2'	System	09 Apr 2021 13:32:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '1'	System	09 Apr 2021 13:32:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '804 (804)'	System	09 Apr 2021 13:32:53

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:34:43
Data point term sent to Coder	System	09 Apr 2021 13:33:55
User entered 'milk of magnesia'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '30'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'once (ONCE)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:33:31
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User entered empty.	System	09 Apr 2021 13:33:31

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User entered empty.	System	09 Apr 2021 13:33:31

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:33
User entered empty.	System	09 Apr 2021 13:33:31

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 14:28:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 14:28:32
Data point term sent to Coder	System	09 Apr 2021 13:34:56
User entered 'diphenhydramine'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:34:12
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User entered empty.	System	09 Apr 2021 13:34:12

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User entered empty.	System	09 Apr 2021 13:34:12

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:50
User entered empty.	System	09 Apr 2021 13:34:12

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 14:48:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 14:48:45
Data point term sent to Coder	System	09 Apr 2021 13:35:57
User entered 'ondansetron'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative nausea'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '4'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:59:46
User closed query 'please verify as 25Mar21 per CM log' (Site from CRA).		12 Apr 2021 22:59:24
Query 'please verify as 25Mar21 per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	12 Apr 2021 21:17:24
User entered '25 Mar 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	12 Apr 2021 21:13:04
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:52
DataPoint Verified.		12 Apr 2021 20:40:29
User opened query 'please verify as 25Mar21 per CM log' (Site from CRA).		12 Apr 2021 20:32:23
User entered '26 Mar 2021' reason for change: Data Entry Error	Sherry Henning (b) (4)	12 Apr 2021 19:45:10
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:35:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User entered empty.	System	09 Apr 2021 13:35:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User entered empty.	System	09 Apr 2021 13:35:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:16
User entered empty.	System	09 Apr 2021 13:35:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:59:38
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:59:38
User signature succeeded.	Richard Glover (b) (4) (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:36:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:36:37
Data point term sent to Coder	System	09 Apr 2021 13:35:57
User entered 'saline flush'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:35:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '3'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '26 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:35:49
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User entered '2'	System	09 Apr 2021 13:35:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User entered '1'	System	09 Apr 2021 13:35:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:35
User entered '804 (804)'	System	09 Apr 2021 13:35:49

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:37:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	09 Apr 2021 13:37:39
Data point term sent to Coder	System	09 Apr 2021 13:36:58
User entered 'docusate sodium'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative constipation'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '100'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:36:21
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User entered '2'	System	09 Apr 2021 13:36:21

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User entered '1'	System	09 Apr 2021 13:36:21

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:57
User entered '804 (804)'	System	09 Apr 2021 13:36:21

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:01:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:01:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
Data point term sent to Coder	System	12 Apr 2021 19:39:06
Coding entries removed.	Sherry Henning (b) (4)	12 Apr 2021 19:38:12
	(b) (4)	
User entered 'CYCLOBENZaprine' reason for change: Data Entry Error	Sherry Henning (b) (4)	12 Apr 2021 19:38:12
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:18:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:18:57
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:37:58
User entered 'cyclobenz'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'muscle spasms, generalized'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '10'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:37:09
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User entered empty.	System	09 Apr 2021 13:37:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User entered empty.	System	09 Apr 2021 13:37:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:17
User entered empty.	System	09 Apr 2021 13:37:09

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:48:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:48:27
Data point term sent to Coder	System	09 Apr 2021 13:38:59
User entered 'cefazolin'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Yes (Y)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'infection prophylaxis'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '2'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'g (g)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'four times daily (QID)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '26 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:38:08
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User entered '4'	System	09 Apr 2021 13:38:08

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User entered '1'	System	09 Apr 2021 13:38:08

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:01:34
User entered '804 (804)'	System	09 Apr 2021 13:38:08

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:48:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:38:59
User entered 'Eliquis'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'atrial fibrillation'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '5'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'twice daily (BID)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '26 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:38:48
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User entered '2'	System	09 Apr 2021 13:38:48

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User entered '1'	System	09 Apr 2021 13:38:48

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:04
User entered '804 (804)'	System	09 Apr 2021 13:38:48

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:39:03
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:39:03
Data point term sent to Coder	System	09 Apr 2021 13:39:59
User entered 'ketorolac'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:39:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '30'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mg (mg)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:39:33
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:39:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:39:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:39:33

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 13:52:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:41:10
User entered 'lactated ringers'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '1000'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'other (OTHER)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'continuous'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:14
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User entered empty.	System	09 Apr 2021 13:40:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User entered empty.	System	09 Apr 2021 13:40:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:40
User entered empty.	System	09 Apr 2021 13:40:14

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
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 17:49:57
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 17:49:57
User signature succeeded.	Richard Glover (b) (4) (b) (4)	16 Apr 2021 15:19:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
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)	09 Apr 2021 13:52:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:52:12
Data point term sent to Coder	System	09 Apr 2021 13:41:06
User entered 'normal saline'	Riley King (b) (4) (b) (4)	09 Apr 2021 13:40:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Worsening osteoarthritis bilateral knees'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '1000'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'mL (mL)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'other (OTHER)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '75 mL/hr'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '25 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '27 Mar 2021'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Riley King (b) (4)	09 Apr 2021 13:40:51
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User entered empty.	System	09 Apr 2021 13:40:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User entered empty.	System	09 Apr 2021 13:40:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:20
User entered empty.	System	09 Apr 2021 13:40:51

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 12:51:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:51:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
Data point term sent to Coder	System	12 Apr 2021 19:50:27
User entered 'oxycodone (5/325)'	Sherry Henning (b) (4) (b) (4)	12 Apr 2021 19:50:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'post operative pain'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'I'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'tablet (TABLET)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered empty.	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '11 Feb 2021'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '0'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered '11 Feb 2021'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:29
User entered 'No (N)'	Sherry Henning (b) (4)	12 Apr 2021 19:50:20
	(b) (4)	

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User entered empty.	System	12 Apr 2021 19:50:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User entered empty.	System	12 Apr 2021 19:50:20

US3062157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:06:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:44:38
User entered empty.	System	12 Apr 2021 19:50:20

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:06:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:14:41
User entered 'Yes (Y)' reason for change: New Information	Sherry Henning (b) (4)	15 Mar 2021 15:27:18
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 14:27:14

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
User closed query 'please obtain hosp records for R knee replacement and add meds to CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:22:01
Query 'please obtain hosp records for R knee replacement and add meds to CM log' answered with 'records are pending' (Site from CRA).	marissa Mueller (b) (4)	17 Mar 2021 15:59:49
	(b) (4)	
User opened query 'please obtain hosp records for R knee replacement and add meds to CM log' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 19:19:47
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:14:54
User entered '11 Feb 2021'	Sherry Henning (b) (4)	15 Mar 2021 15:28:37
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:14:54
User entered 'right knee replacement'	Sherry Henning (b) (4)	15 Mar 2021 15:28:37
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:14:54
User entered 'Medical History (MH)'	Sherry Henning (b) (4)	15 Mar 2021 15:28:37
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:14:54
User entered empty.	Sherry Henning (b) (4)	15 Mar 2021 15:28:37
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:03:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
User entered '25 Mar 2021'	Riley King (b) (4)	29 Mar 2021 19:18:28
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:03:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
User entered 'left knee replacement'	(b) (4) Riley King (b) (4) (b) (4)	29 Mar 2021 19:18:28

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:03:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	29 Mar 2021 19:18:28

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:03:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:39:51
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Mar 2021 19:18:28
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:30
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered '27 Jan 2021'	Riley King (b) (4)	09 Apr 2021 14:17:21
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:30
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered 'CT left knee without contrast'	Riley King (b) (4)	09 Apr 2021 14:17:21
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:30
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered 'Adverse Event (AE)'	Riley King (b) (4)	09 Apr 2021 14:17:21
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:30
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:17:21
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:32
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered '27 Jan 2021'	Riley King (b) (4)	09 Apr 2021 14:17:47
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:32
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered 'CT right knee without contrast'	Riley King (b) (4)	09 Apr 2021 14:17:47
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:32
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered 'Adverse Event (AE)'	Riley King (b) (4)	09 Apr 2021 14:17:47
	(b) (4)	

US3062157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:32
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:09
User entered empty.	Riley King (b) (4)	09 Apr 2021 14:17:47
	(b) (4)	

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered '30/Mar/2021 11:47'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:44

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)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
	(b) (4)	
User entered '07/Apr/2021 09:25'	System	07 Apr 2021 16:25:12

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:44

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:25:12

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:23:29
User entered '12/Apr/2021 15:17'	System	12 Apr 2021 15:17:25

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:44

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 15:19:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:40:32
DataPoint Verified.		12 Apr 2021 20:23:29
User entered 'I'		12 Apr 2021 15:17:25

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
User entered '12/Apr/2021 20:40'	System	12 Apr 2021 20:40:47

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:06:44

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 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 21:21:03
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 20:40:47

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
User entered '13/Apr/2021 21:21'	System	13 Apr 2021 21:21:25

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:06:44

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 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 13:34:54
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 21:21:25

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
User entered '14/Apr/2021 08:35'	System	14 Apr 2021 13:35:04

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:06:44

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)	20 Apr 2021 15:48:10
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:36:28
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 13:35:04

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered	System	30 Mar 2021 16:46:57
'USA-US090-2021-MRNA-1273-P301000011'		

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'No (N)'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Richard'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Glover'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '700 Medical Center Dr.'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'Newton'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered 'KS'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:09
User entered '67114'	System	30 Mar 2021 16:46:57

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:40:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:13:36
User entered 'US'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Apr 2021 15:48:25
User entered '6'	System	14 Apr 2021 13:35:04
User entered '5'	System	13 Apr 2021 21:21:25
User entered '4'	System	12 Apr 2021 20:40:47
User entered '3'	System	12 Apr 2021 15:17:25
User entered '2'	System	07 Apr 2021 16:25:12
User entered '1'	System	30 Mar 2021 16:47:18

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:06:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:47:32
User entered '20/Apr/2021 15:48'	System	20 Apr 2021 15:48:25

US3062157

Folder: SAE USA-US090-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:06:44

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)	23 Apr 2021 15:53:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:47:32
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 15:48:25