

US3062265 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:01:07

All time stamps listed in this document are displayed in GMT

US3062265

Form: Participant Creation

Data signed: (b) (4) 15 Mar 2021 21:46:07

Generated On: 09 Jun 2021 15:01:07

Participant ID

US3062265

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

US3062265

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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

Visit date (dd MMM yyyy)	15 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	SCRN
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US3062265

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Date of Informed Consent (<i>dd MMM yyyy</i>)	15 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 21:46:12

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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 Mar 2021 21:46:12

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Condition	RIGHT LEG PAIN
Start date (dd MMM yyyy)	UN FEB 2020
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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Condition	ALCOHOL ABUSE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Condition	ALCOHOL WITHDRAWAL SEIZURES, RECURRENT
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 13:50
Height (<i>xxx.x</i>)	174.0 cm
Weight (<i>xxx.x</i>)	116.0 kg
BMI (<i>xxx.x</i>)	38.31418 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 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 Mar 2021 21:46:12

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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 Mar 2021 21:46:12

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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

Visit date (dd MMM yyyy)	15 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 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

What was the date of randomization? (dd MMM yyyy) 15 AUG 2020

What was the participant's randomization number? 104826

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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)	15 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 13:50
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)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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)	15 AUG 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 15:38
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)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	105 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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) 15 AUG 2020

What was the treatment time? (00:00-23:59) 15:05 (24 HR)

Treatment Date and Time (derived) 15 AUG 2020 15:05

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 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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

Collection date (dd MMM yyyy)	15 AUG 2020
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Collection time (00:00-23:59)	14:28 (24 HR)
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Collection date and time (derived)	15 AUG 2020 14:28
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US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)			15 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:32	15 AUG 2020 14:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

15 AUG 2020 15:45

PC Open Date & Time

15 AUG 2020 15:25

PC Close Date & Time

15 AUG 2020 17:55

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 15 AUG 2020 18:50

PC Close Date & Time 16 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

16 AUG 2020 18:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

98.7 °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

17 AUG 2020 21:48

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

96.6 °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

19 AUG 2020 17:11

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 AUG 2020 18:30

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

98.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 21:22

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

15 AUG 2020 15:45

PC Open Date & Time

15 AUG 2020 15:25

PC Close Date & Time

15 AUG 2020 17:55

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 18:50

PC Close Date & Time

16 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

16 AUG 2020 18:42

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

17 AUG 2020 21:49

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

18 AUG 2020 18:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

19 AUG 2020 17:11

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

20 AUG 2020 18:31

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

21 AUG 2020 21:23

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 ☐

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 15:46
PC Open Date & Time	15 AUG 2020 15:25
PC Close Date & Time	15 AUG 2020 17:55

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 ☐

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 18:50

PC Close Date & Time

16 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 3609

EAB) (1725)

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

49 of 3609

EAB) (1725)

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:49
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 ☒

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 ☒

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EAB) (1725)

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US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 17:12
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 ☒

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:32
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 ☒

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 21:23
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3062265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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)	23 SEP 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:12
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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)	23 SEP 2020
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 16:27
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3062265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 15:55 (24 HR)

Treatment Date and Time (derived) 23 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

US3062265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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

Collection date (dd MMM yyyy)	23 SEP 2020
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Collection time (00:00-23:59)	14:45 (24 HR)
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Collection date and time (derived)	23 SEP 2020 14:45
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US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:48	23 SEP 2020 14:48
Nasopharyngeal Swab 2	No		

US3062265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 16:31

PC Open Date & Time

23 SEP 2020 16:15

PC Close Date & Time

23 SEP 2020 18:45

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 SEP 2020 19:40

PC Close Date & Time 24 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

25 SEP 2020 08:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 SEP 2020 08:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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.

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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.

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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

28 SEP 2020 22:39

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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.

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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

97.6 °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

30 SEP 2020 08:10

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 16:31

PC Open Date & Time

23 SEP 2020 16:15

PC Close Date & Time

23 SEP 2020 18:45

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 19:40

PC Close Date & Time

24 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

25 SEP 2020 08:50

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

28 SEP 2020 08:41

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

28 SEP 2020 22:40

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

30 SEP 2020 08:10

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 ☐

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 16:31
PC Open Date & Time	23 SEP 2020 16:15
PC Close Date & Time	23 SEP 2020 18:45

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 ☐

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 19:40

PC Close Date & Time

24 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 08:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

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EAB) (1725)

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 08:41
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 ☒

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 22:40
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 ☒

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 08:11
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments
If Contact Not Made, please provide Comments

UNABLE TO CONTACT SUBJECT
AFTER MULTIPLE ATTEMPTS.
PROTOCOL DEVIATION HAS
BEEN WRITTEN.

US3062265

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 21:46:13

Generated On: 09 Jun 2021 15:01:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 21:46:13

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:11
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 21:46:13

Generated On: 09 Jun 2021 15:01:07

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.

US3062265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 21:46:13

Generated On: 09 Jun 2021 15:01:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

11:38 (24 HR)

Collection date and time (derived)

22 OCT 2020 11:38

US3062265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:13

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 11:44:55

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 <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	29 OCT 2020 13:24:40
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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°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="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"/>

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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°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="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"/>

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3062265

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:01:07

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

US3062265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

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

SUBJECT WITHDRAWN PRIOR
TO CALL

If Contact Not Made, please provide Comments

US3062265

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3062265

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:01:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3062265

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3062265

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

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

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3062265

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3062265

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:07

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3062265

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 21:46:09

Generated On: 09 Jun 2021 15:01:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	USA-US090-2020-MRNA-1273-P30 1000002
Adverse event	WORSENING OF ALCOHOL ABUSE
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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

SUBJECT IN FOR DAY 29 VISIT.
DURING VISIT, SUBJECT
REPORTS THAT HE WAS
RELEASED FROM "REHAB" THIS
MORNING. AFTER DISCUSSION
WITH SUBJECT, IT APPEARS
THAT THE SUBJECT HAD BEEN
HOSPITALIZED FOR DETOX.
SUBJECT REPORTED THE
ALCOHOL ABUSE HAD BEEN A
PROBLEM SINCE 6/15/2020 AND
DECIDED TO GO TO THE
EMERGENCY ROOM ON
9/17/2020. EPIP SUBMITTED AND
SUBJECT ALLOWED TO
CONTINUE IN STUDY. RELEASE
OF RECORDS SIGNED BY
SUBJECT FOR EMERGENCY
ROOM VISIT AND DETOX
CENTER. SUBJECT REPORTS
THAT HE WAS NOT GIVEN ANY
NEW MEDICATIONS. 10/26/2020
RECORDS RECEIVED FROM
SUBSTANCE ABUSE CENTER.
IN RECORDS, IT IS NOTED THAT
SUBJECT'S TRIGGERS FOR
ALCOHOL USE DAILY ARE
PHYSICAL PAIN AND MORNING
WITHDRAWAL SYMPTOMS.
SUBJECT HAD ATTENDED
TREATMENT FOR ALCOHOL
ABUSE IN THE PAST. THE
LONGEST PERIOD OF SOBRIETY
IS REPORTED TO BE 6 YEARS.

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

DURING HOSPITALIZATION
AND TREATMENT CENTER
ADMISSION, SUBJECT WAS NOT
GIVEN ANY MEDICATIONS TO
TREAT THE ALCOHOL ABUSE.
SUBJECT WAS DISCHARGED TO
HIS PRIVATE HOME ON
9/23/2020 WITH PLANS TO
FOLLOW UP WITH A LOCAL
OUTPATIENT TREATMENT
CENTER.

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

US3062265

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	USA-US090-2020-MRNA-1273-P30 1000006
Adverse event	CHEST PAIN - MUSCULOSKELETAL
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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	20 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3062265

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

SUBJECT HAD ACUTE ALCOHOL INTOXICATION AND FELL AT HOME. HE WAS TAKEN TO THE EMERGENCY ROOM FOR THE INJURIES SUSTAINED IN THE FALL. WHILE SUBJECT WAS BEING CARED FOR IN THE EMERGENCY ROOM, HE BEGAN TO HAVE CHEST PAIN. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR OBSERVATION DUE TO CHEST PAIN. ON 10/13/2020, SUBJECT HAD SERIAL TROPONINS DRAWN. ALL WERE NEGATIVE. HE ALSO HAD A CHEST X-RAY. THE RESULTS OF THE CXR WAS "NO ACUTE CARDIOPULMONARY PROCESS". SUBJECT HAD 2 EKGS WHILE IN THE EMERGENCY ROOM. THE FIRST EKG WAS SINUS RHYTHM NO STEMI. THE SECOND EKG WAS SINUS TACHYCARDIA NO STEMI. A NUMBER OF CT SCANS WERE PERFORMED WHILE SUBJECT WAS IN THE EMERGENCY ROOM DUE TO THE FALL. SUBJECT HAD CT OF HEAD, C-SPINE, LUMBAR SPINE, THORACIC SPINE, ABDOMEN/PELVIS. NO SIGNIFICANT FINDINGS RELATED TO THE CHEST PAIN WERE DIAGNOSED FROM THE

US3062265

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

CT SCANS. SUBJECT ALSO HAD
A NEGATIVE³ DRUG SCREEN
FOR ILLICIT DRUGS. THE
CHEST PAIN HAD ENDED
WHILE SUBJECT WAS STILL IN
THE EMERGENCY ROOM. THE
SUBJECT REMAINED IN THE
HOSPITAL OVERNIGHT TO
OBSERVE DUE TO CHEST PAIN.

SUBJECT WAS DISCHARGED
FROM THE HOSPITAL IN
STABLE CONDITION ON
10/20/2020. CONMEDS WERE
UPDATED PER MEDICAL
RECORDS. SEE SAE OF
ALCOHOL WITHDRAWAL
SYMPTOMS TO EXPLAIN
RECOVERED DATE VS.
DISCHARGE DATE.

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

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

LEFT PERIORBITAL
ECCHYMOSIS

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	USA-US090-2020-MRNA-1273-P30 1000006
Adverse event	ALCOHOL WITHDRAWAL SYMPTOMS
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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	20 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (4)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

SUBJECT WAS ADMITTED FOR
OBSERVATION FOR CHEST
PAIN ON 10/13/2020. AT THE
TIME OF ADMISSION, SUBJECT
HAD ACUTE ALCOHOL
INTOXICATION. SUBJECT
REPORTED THAT HE HAS A
HISTORY OF ALCOHOL
WITHDRAWAL SEIZURES.
SUBJECT WAS CHANGED TO
INPATIENT STATUS DUE TO
ALCOHOL WITHDRAWAL
SYMPTOMS. SUBJECT'S
ALCOHOL LEVEL UPON
ADMISSION TO THE
EMERGENCY ROOM ON
10/13/2020 WAS 404. SUBJECT
WAS GIVEN FLUIDS AND
MONITORED FOR SYMPTOMS
OF ALCOHOL WITHDRAWAL.
ON 10/20/2020, SUBJECT
REMAINS HOSPITALIZED. WAS
GIVEN ATIVAN DURING
HOSPITALIZATION DUE TO
CLINICAL INSTITUTE
WITHDRAWAL ASSESSMENT
SCORES. AWAITING RECORDS
TO GIVE FURTHER DETAILS.

UPDATED START DATE PER
MEDICAL RECORDS. SUBJECT
WAS DISCHARGED FROM THE
HOSPITAL IN STABLE
CONDITION ON 10/20/2020.
CONMEDS WERE

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

UPDATED PER MEDICAL
RECORDS UPDATE 11/6/2020
PER HOSPITAL RECORDS,
SUBJECT'S WITHDRAWAL
SYMPTOMS WERE TREMORS,
HEADACHE, NAUSEA,
VOMITING, ANXIETY AND
DIARRHEA. CIWA SCALE
UTILIZED TO MANAGE
WITHDRAWAL SYMPTOMS
WHILE HOSPITALIZED

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	TRANSAMINITIS
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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

HYPOKALEMIA

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (6)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

HYPERGLYCEMIA

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (7)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	VERTIGO
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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

ACUTE ALCOHOL
INTOXICATION

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

GENERALIZED 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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

LEFT PERIORBITAL
HEMATOMA

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

SCALP ABRASIONS

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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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Form: Adverse Events (12)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	VOMITING
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)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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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Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

LEFT ELBOW FRACTURE

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (14)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	THROMBOCYTOPENIA
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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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AEID

Adverse event

CHRONIC SINUSITIS

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (17)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

DEGENERATIVE SPONDYLOSIS

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (18)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

RIGHT HIP DEGENERATIVE
CHANGES

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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 (20)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

WHEEZING

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)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

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 (20)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	USA-US090-2020-MRNA-1273-P30 1000009
Adverse event	ALCOHOL WITHDRAWAL SYMPTOMS
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	02 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (21)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

ON 10/28/2020, SUBJECT CALLED THE SITE TO REPORT THAT HE WAS HOSPITALIZED AGAIN. SUBJECT REPORTS THAT HE WAS BROUGHT TO THE EMERGENCY ROOM BY EMS AFTER FALLING ON THE ICE WHILE INTOXICATED. SUBJECT WAS EVALUATED IN THE EMERGENCY ROOM. WAS ADMITTED TO THE HOSPITAL FOR OBSERVATION FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT PROTOCOL IMPLEMENTED FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. AN ALCOHOL LEVEL INDICATED THAT SUBJECT'S ALCOHOL LEVEL WAS 450 WHILE IN THE EMERGENCY ROOM. RECORDS TO BE COLLECTED FROM HOSPITAL AFTER SUBJECT IS DISMISSED. ACCORDING TO SUBJECT, PLAN TO DISCHARGE POTENTIALLY ON 10/29/2020.

SUBJECT WAS TAKEN TO THE EMERGENCY ROOM ON 10/27/2020 AFTER FALLING WHILE INTOXICATED. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR ALCOHOL

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 15 Mar 2021 21:46:08

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WITHDRAWAL SYMPTOMS. HE RECEIVED SERAX AND ATIVAN FOR THE WITHDRAWAL SYMPTOMS BASED ON THE CIWA SCORING SYSTEM. SUBJECT REMAINED HOSPITALIZED THROUGH 11/2/2020. HE WAS DISCHARGED HOME. PER HOSPITAL RECORDS, SUBJECT PLANS TO STAY WITH A FRIEND UNTIL HE IS ABLE TO ATTEND INPATIENT REHABILITATION. SUBJECT WAS DISCHARGED IN STABLE CONDITION. PER HOSPITAL RECORDS, SUBJECT REPORTS FALLING OUTSIDE OF HIS HOME. HE STATED HE STRUCK HIS HEAD. COMPLAINTS OF PAIN IN NECK, MID BACK, LOW BACK, AND RIGHT LOWER QUADRANT UPON ADMISSION. SUBJECT APPEARED INTOXICATED ON ADMISSION. SUBJECT'S ALCOHOL LEVEL WAS 450 MG/DL WITH A REFERENCE RANGE OF <10 MG/DL. VITAL SIGNS ON ADMISSION WERE AS FOLLOWS: TEMPERATURE 97.8 F, PULSE RATE 100 BPM, RESPIRATORY RATE 16 BREATHS PER MINUTE, BLOOD PRESSURE 115/74 MMHG, AND 98% O2 SATURATION. SUBJECT

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Form: Adverse Events (21)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

REQUESTED TO BE ADMITTED
TO THE HOSPITAL FOR DETOX
AND PLACEMENT FOR
ALCOHOLISM. SUBJECT
APPEARED STABLE AND
RESTING COMFORTABLY UPON
ADMISSION. NO SIGNS OF
TRAUMA NOTED. SUBJECT
STATED FRACTURES FOUND
WERE OLD FRACTURES.
SUBJECT DISMISSED ON
11/02/2020 AND PLANNED TO
STAY WITH A FRIEND UNTIL
ACCEPTED INTO INPATIENT
REHAB.

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

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

T11 AND T12 END PLATE
FRACTURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

ACUTE ALCOHOL
INTOXICATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

RIGHT DISTAL 3RD CLAVICLE
FRACTURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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 <input type="radio"/>
	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 (26)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

HYPONATREMIA

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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (26)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (27)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event HYPOPHOSPHATEMIA

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) 28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 29 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization 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 (27)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (28)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

URINARY RETENTION

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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (28)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (29)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

JOINT PAIN, 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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (29)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (30)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

BACK 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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (30)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (31)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	WHEEZING
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 NOV 2020
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 (31)

Data signed: (b) (4) 15 Mar 2021 21:46:08

Generated On: 09 Jun 2021 15:01:07

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)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

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

Yes ☒

No ☐

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

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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 (1)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication PREGABALIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT LEG PAIN

Dose per administration 75

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) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUN 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 (3)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (3)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 (4)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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 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)	13 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)	18 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 (5)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication VITAMIN B1

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication FOLATE

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 (6)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 20 OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 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 (9)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication LIDODERM 5% PATCH

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 1

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

If dose unit is Other, specify PATCH

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) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN -
MUSCULOSKELETAL

Dose per administration 324

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 (14)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication APRESOLINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (15)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication 1/2 NORMAL SALINE 20
POTASSIUM CHLORIDE (20MCG
POTASSIUM CHLORIDE)

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication 1/2 NORMAL SALINE 20
POTASSIUM CHLORIDE (20MCG
POTASSIUM CHLORIDE)

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication SUBLIMAZE

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (18)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 (19)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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 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)	13 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)	13 OCT 2020	
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 (20)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication VITAMIN B1 200MG,
MAGNESIUM 1G, MULTIPLE
VITAMIN INJECTION 10ML, D5W
1000ML

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication VENTOLIN (90 MCG)

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

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 (21)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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)		13 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 (22)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication PROVENTIL (2.5MG/3ML)

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

Dose per administration 1

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

If dose unit is Other, specify UNIT

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) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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		NEBULIZER
Start date (dd MMM yyyy)		13 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)		20 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 (23)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication BROVANA (15MCG/2ML)

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

Dose per administration 1

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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Generated On: 09 Jun 2021 15:01:07

	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	NEBULIZER	
Start date (dd MMM yyyy)	13 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)	20 OCT 2020	
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 (24)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication PULMICORT (0.25MG/2ML)

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

Dose per administration 1

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

If dose unit is Other, specify UNIT

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) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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	NEBULIZER	
Start date (dd MMM yyyy)	13 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)	20 OCT 2020	
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 (25)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication 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) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication PERCOCET (5MG/325MG)
ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (26)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		13 OCT 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 (27)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication POTASSIUM CHLORIDE (K-DUR)

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

Dose per administration 40

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

If dose unit is Other, specify MILLIEQUIVALENT

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)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (28)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication D5W 1000ML, VITAMIN
B-1200MG, MAGNESIUM 1GM,
MULTIVITAMIN 10ML

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	Transdermal	<input type="checkbox"/>
	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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

EVERY 1 HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication SERAX (OXAZEPAM)

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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

EVERY 8 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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Name of Medication FOLATE

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication VITAMIN B1

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (36)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication ACUTE ALCOHOL
INTOXICATION

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 1 HOUR

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) 15 Mar 2021 21:46:10

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication BROVANA

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

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)

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Data signed: (b) (4) 15 Mar 2021 21:46:10

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	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	NEBULIZER	
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
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 (39)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication LIDODERM 5% PATCH

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 1

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

If dose unit is Other, specify PATCH

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 (39)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

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Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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 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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 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 (43)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication POTASIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MILLIEQUIVALENTS

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 (43)

Data signed: (b) (4) 15 Mar 2021 21:46:10

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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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
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 (44)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (44)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	28 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)		28 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 (45)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (45)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication POTASSIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	28 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)	29 OCT 2020	
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"/>

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication OXYCODONE IMMEDIATE
RELEASE

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED 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 (48)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication URINARY RETENTION

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWAL SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 15 Mar 2021 21:46:10

Generated On: 09 Jun 2021 15:01:07

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
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"/>

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 31 Mar 2021 20:44:40

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 OCT 2020	EKG	Adverse Event	
13 OCT 2020	EKG	Adverse Event	
13 OCT 2020	CHEST X-RAY	Adverse Event	
13 OCT 2020	X-RAY RIGHT ELBOW	Diagnostic	
13 OCT 2020	CT HEAD WITHOUT CONTRAST	Adverse Event	
13 OCT 2020	CT MAXILLOFACIAL WITHOUT CONTRAST	Adverse Event	
13 OCT 2020	CT CERVICAL SPINE WITHOUT CONTRAST	Adverse Event	
13 OCT 2020	CT THORACIC SPINE WITHOUT CONTRAST	Adverse Event	
13 OCT 2020	CT LUMBAR SPINE WITHOUT CONTRAST	Adverse Event	
13 OCT 2020	X-RAY RIGHT HIP	Adverse Event	
13 OCT 2020	CT LEFT ELBOW	Adverse Event	
13 OCT 2020	CT ABDOMEN/PELVIS	Adverse Event	
13 OCT 2020	X-RAY LEFT ELBOW	Adverse Event	
27 OCT 2020	CT ABDOMIN/PELVIS	Adverse Event	
27 OCT 2020	CT THORACIC SPINE	Adverse Event	
27 OCT 2020	CT HEAD	Adverse Event	
28 OCT 2020	FOLEY CATHETER PLACEMENT	Adverse Event	
27 OCT 2020	CT CERVICAL SPINE	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Data signed: (b) (4) 31 Mar 2021 20:44:40

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	X-RAY RIGHT SHOULDER	Adverse Event	
27 OCT 2020	CHEST X-RAY	Adverse Event	
13 OCT 2020	CT LUMBAR SPINE WITHOUT CONTRAST	Adverse Event	

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

Date of study discontinuation/completion (dd MMM yyyy) 20 NOV 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input checked="" type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify INACCURATE DATA AND TO ALLOW TIME FOR SUBJECT TO GET HEALTH IN ORDER.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5
Date of submission (Pre-filled from custom function)	25/SEP/2020 08:16
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:59
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5
Date of submission (Pre-filled from custom function)	26/OCT/2020 11:27
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5
Date of submission (Pre-filled from custom function)	27/OCT/2020 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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Mar 2021 21:46:11

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000002
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)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 16:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/OCT/2020 19:35
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/OCT/2020 14:17
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/OCT/2020 13:37
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/NOV/2020 10:37
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/NOV/2020 10:13
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:23
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

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000009
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)	2

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000009
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)	2
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Mar 2021 21:46:12

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2020-MRNA-1273-P301000009
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)	2
Date of submission (Pre-filled from custom function)	07/JAN/2021 14:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3062265 (Prod: Alliance for Multispecialty Research, LLC)

US3062265

Form: Participant Creation

Generated On: 09 Jun 2021 15:01:07

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'US3062265'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 18:59:09

US3062265

Form: Participant Creation

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:00

US3062265

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 18:59:10

US3062265

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:00

US3062265

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'SCRN'	System	15 Aug 2020 20:09:00

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 18:59:11

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '56'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'YEARS'	System	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '56'	System	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Male (M)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'I'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Janna Martinez (b) (4)	15 Aug 2020 20:09:12

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'Aug 2020'	System	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2020'	System	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Amendment 2 (2)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:34

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 18:59:10

US3062265

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:01:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'please consider adding chronic asthma to med history per hosp records in source' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:47:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:51:02
Query 'please consider adding chronic asthma to med history per hosp records in source' answered with 'indication for medications are documented as wheezing' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 22:53:58
	(b) (4)	
User opened query 'please consider adding chronic asthma to med history per hosp records in source' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:00:59
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:47:11
	(b) (4)	

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 20:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:49:15
Data point term sent to Coder	System	17 Aug 2020 20:48:03
User entered 'Hypertension'	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'un UNK 2005'	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'Jan 2005'	System	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '2005'	System	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	17 Aug 2020 20:47:31

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
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: Pain in extremity, LLT: Unilateral leg pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 07:11:23
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:11:23
Data point term sent to Coder	System	17 Aug 2020 20:48:04
User entered 'Right Leg Pain'	Colton King (b) (4) (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'un Feb 2020'	Colton King (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'Feb 2020'	System	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '2020'	System	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	17 Aug 2020 20:47:58

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:02:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:02:43
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 21:01:58
User entered 'Alcohol abuse'	Sherry Henning (b) (4)	24 Sep 2020 21:01:15
	(b) (4)	

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'un UNK 2000' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:40:09
User entered '15 Jun 2020'	Sherry Henning (b) (4)	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'Jan 2000'	System	26 Oct 2020 20:40:09
User entered 'Jun 2020'	System	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '2000'	System	26 Oct 2020 20:40:09
User entered '2020'	System	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	24 Sep 2020 21:01:15

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Alcoholic seizure, LLT: Alcohol withdrawal seizure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Nov 2020 23:26:23
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:26:23
Data point term sent to Coder	System	06 Nov 2020 18:41:03
User entered 'Alcohol Withdrawal Seizures, Recurrent'	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'un UNK 2000'	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Jeri King (b) (4)	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'Jan 2000'	System	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '2000'	System	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	06 Nov 2020 18:40:24

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '13:50'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 13:50'	System	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '174.0' cm	(b) (4) Colton King (b) (4)	17 Aug 2020 20:49:07
DataPoint set to visible.	(b) (4) System	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '116.0' kg	Colton King (b) (4)	17 Aug 2020 20:49:07
DataPoint set to visible.	System	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
Amendment Manager: User entered '38.31418'	System	16 Sep 2020 23:58:52
User entered '38.3'	System	17 Aug 2020 20:49:07
DataPoint set to visible.	System	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'kg/m2'	System	17 Aug 2020 20:49:07
DataPoint set to visible.	System	15 Aug 2020 20:09:38

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:20
User entered '98.0' F	Colton King (b) (4)	17 Aug 2020 20:49:07
	(b) (4)	

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:20
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	17 Aug 2020 20:49:07
	(b) (4)	

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Aug 2020 18:32:20
User entered '105'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:20
User entered '16'	Colton King (b) (4)	17 Aug 2020 20:49:07
	(b) (4)	

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:20
User entered '134'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Aug 2020 18:32:20
User entered '13'	Colton King (b) (4)	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:49:07

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22

US3062265

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22

US3062265

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:33:10
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:49:12
	(b) (4)	

US3062265

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '15 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:33:10
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:49:12
	(b) (4)	

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'I'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:50:52

US3062265

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:54

US3062265

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Janna Martinez (b) (4)	15 Aug 2020 20:09:54

US3062265

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	15 Aug 2020 20:09:54

US3062265

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'VISIT1'	System	15 Aug 2020 20:09:54

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 19:39:16

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:51:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:51:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 19:39:16
User entered '104826' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 19:39:16

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 19:39:16

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'please verify hospital record dated 13Oct re tobacco abuse and possible COPD diagnosis' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:27:39
Query 'please verify hospital record dated 13Oct re tobacco abuse and possible COPD diagnosis' answered with 'records state "possible" post screening. Therefore, at screening there was no known dx of COPD' (Site from CRA).	marissa Mueller (b) (4)	19 Nov 2020 16:11:44
	(b) (4)	
User opened query 'please verify hospital record dated 13Oct re tobacco abuse and possible COPD diagnosis' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:50:03
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:22
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Query 'please verify as yes per hosp record-patient stated MH of cardiac arrhythmia, CHF, CAD, MI and valvular disease' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:56:21
User opened query 'please verify as yes per hosp record-patient stated MH of cardiac arrhythmia, CHF, CAD, MI and valvular disease' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:54:44
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:22
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:22
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:22

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:22

US3062265

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:31:27

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '174.0' cm	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '116' kg	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '174.0' cm	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '116' kg	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '13:50'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 13:50'	System	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '98.0' F	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Oral (Oral)'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '105'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '16'	Colton King (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '134' reason for change: Data Entry Error	Colton King (b) (4)	17 Aug 2020 20:55:57
	(b) (4)	
User entered '103'	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 20:55:57
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Aug 2020 20:55:57
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	17 Aug 2020 20:55:57
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	17 Aug 2020 20:55:57
User entered '94' reason for change: Data Entry Error	Colton King (b) (4)	17 Aug 2020 20:55:57
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 20:54:58
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	17 Aug 2020 20:54:58
User entered '134'	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '174.0' cm	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:32:46
User entered '116' kg	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 07:12:24
Query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose and update as appropriate. ' answered with 'Apologies for the transcription error. Time of assessment corrected.' (Site from DM).	Sherry Henning (b) (4)	23 Sep 2020 21:01:39
User entered '15:38' reason for change: Data Entry Error	Sherry Henning (b) (4)	23 Sep 2020 21:00:39
User opened query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:41:18
Query 'Requery: Could you please confirm if it is NCS/CS.If CS kindly update appropriately.' canceled (Site from DM).		19 Aug 2020 07:49:29
User opened query 'Requery: Could you please confirm if it is NCS/CS.If CS kindly update appropriately.' (Site from DM).		19 Aug 2020 04:02:38
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).		19 Aug 2020 04:01:45
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 per perotocol ' (Site from System).	Colton King (b) (4)	17 Aug 2020 20:59:41
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).		17 Aug 2020 20:59:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:59:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 20:59:20
User entered '13:54' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	17 Aug 2020 20:59:20
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:58
User entered empty.	Colton King (b) (4) (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 15:38'	System	23 Sep 2020 21:00:39
User entered '15 Aug 2020 13:54'	System	17 Aug 2020 20:59:20
User entered empty.	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	17 Aug 2020 20:59:20
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered by data change (Site from System).	System	17 Aug 2020 20:59:20
User entered '98.6' F reason for change: Data Entry Error	Colton King (b) (4)	17 Aug 2020 20:59:20
	(b) (4)	
User opened query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	17 Aug 2020 20:54:58
User entered '103' F	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Oral (Oral)'	Colton King (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '98'	Colton King (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '18'	Colton King (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '151'	Colton King (b) (4)	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:54:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '105' reason for change: Data Entry Error	Sherry Henning (b) (4)	23 Sep 2020 21:00:39
	(b) (4)	
User closed query 'Per CDM kindly confirm if it is NCS/CS.If CS update AE section appropriately.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:34:58
Query 'Per CDM kindly confirm if it is NCS/CS.If CS update AE section appropriately.' answered with 'NCS as per PI' (Site from DM).	Colton King (b) (4)	20 Aug 2020 22:17:52
	(b) (4)	
User opened query 'Per CDM kindly confirm if it is NCS/CS.If CS update AE section appropriately.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 03:57:14
Query 'Per CDM kindly confirm if is NCS/CS, if CS kindly update appropriately.' canceled (Site from DM).		20 Aug 2020 03:56:15
User opened query 'Per CDM kindly confirm if is NCS/CS, if CS kindly update appropriately.' (Site from DM).		20 Aug 2020 03:56:06
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Aug 2020 03:54:02
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct as entered ' (Site from System).	Colton King (b) (4)	17 Aug 2020 20:59:57
	(b) (4)	
User entered '103' reason for change: Data Entry Error	Colton King (b) (4)	17 Aug 2020 20:59:20
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		17 Aug 2020 20:54:58
User entered '105'	Colton King (b) (4)	17 Aug 2020 20:54:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	17 Aug 2020 20:54:58

US3062265

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:33:24
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 18:33:24
	(b) (4)	
User entered '15 Aug 2020'	Colton King (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'MRNA-1273 OR PLACEBO'	System	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15:05'	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 15:05'	System	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Left Arm (LEFT ARM)'	Janna Martinez (b) (4)	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'ONCE'	System	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'INTRAMUSCULAR'	System	15 Aug 2020 20:10:47

US3062265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:51:46

US3062265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15 Aug 2020'	Colton King (b) (4)	17 Aug 2020 20:51:46

US3062265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14:28'	Colton King (b) (4)	17 Aug 2020 20:51:46

US3062265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 14:28'	System	17 Aug 2020 20:51:46

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	17 Aug 2020 20:52:17
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Aug 2020 20:52:17
User entered '15 Aug 2020' reason for change: Data Entry Error	Colton King (b) (4)	17 Aug 2020 20:52:17
	(b) (4)	
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	17 Aug 2020 20:52:02
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:52:02
	(b) (4)	

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14:32'	(b) (4) Colton King (b) (4) (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '15 Aug 2020 14:32'	System	17 Aug 2020 20:52:17
User entered empty.	System	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	17 Aug 2020 20:52:02

US3062265

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:52:26

US3062265

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'I'	System	17 Aug 2020 20:52:26

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:44:46', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1b5b472d-5ef7-4d7b-9982-a8d1f159e3f5'	System	15 Aug 2020 20:45:16
User entered 'Yes (Y)'	System	15 Aug 2020 20:45:16

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:44:57', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1b5b472d-5ef7-4d7b-9982-a8d1f159e3f5'	System	15 Aug 2020 20:45:16
User entered '98.6'	System	15 Aug 2020 20:45:16

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:06', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1b5b472d-5ef7-4d7b-9982-a8d1f159e3f5'	System	15 Aug 2020 20:45:16
User entered 'No (N)'	System	15 Aug 2020 20:45:16

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:13', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1b5b472d-5ef7-4d7b-9982-a8d1f159e3f5'	System	15 Aug 2020 20:45:16
User entered '15 Aug 2020 15:45'	System	15 Aug 2020 20:45:16

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 15:25'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 17:55'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 18:50'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 2'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T17:18:29', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1079159e-9859-4e5b-b87d-7588864519e8'	System	16 Aug 2020 23:41:54
User entered 'Yes (Y)'	System	16 Aug 2020 23:41:54

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:41:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1079159e-9859-4e5b-b87d-7588864519e8'	System	16 Aug 2020 23:41:54
User entered '98.6'	System	16 Aug 2020 23:41:54

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:41:43', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1079159e-9859-4e5b-b87d-7588864519e8'	System	16 Aug 2020 23:41:54
User entered 'No (N)'	System	16 Aug 2020 23:41:54

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:41:49', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1079159e-9859-4e5b-b87d-7588864519e8'	System	16 Aug 2020 23:41:54
User entered '16 Aug 2020 18:41'	System	16 Aug 2020 23:41:54

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 3'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:47:59', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a7724033-b693-4b19-8cc0-e3370900302e'	System	18 Aug 2020 02:48:36
User entered 'Yes (Y)'	System	18 Aug 2020 02:48:36

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a7724033-b693-4b19-8cc0-e3370900302e' User entered '98.7'	System	18 Aug 2020 02:48:36
	System	18 Aug 2020 02:48:36

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:22', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a7724033-b693-4b19-8cc0-e3370900302e'	System	18 Aug 2020 02:48:36
User entered 'No (N)'	System	18 Aug 2020 02:48:36

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a7724033-b693-4b19-8cc0-e3370900302e'	System	18 Aug 2020 02:48:36
User entered '17 Aug 2020 21:48'	System	18 Aug 2020 02:48:36

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 4'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:20:46', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1fdb80d-49e5-45ff-ab17-1aa65ee8c682'	System	18 Aug 2020 23:21:15
User entered 'Yes (Y)'	System	18 Aug 2020 23:21:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:20:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1fdb80d-49e5-45ff-ab17-1aa65ee8c682'	System	18 Aug 2020 23:21:15
User entered '98.7'	System	18 Aug 2020 23:21:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:06', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1fdb80d-49e5-45ff-ab17-1aa65ee8c682'	System	18 Aug 2020 23:21:15
User entered 'No (N)'	System	18 Aug 2020 23:21:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1fdb80d-49e5-45ff-ab17-1aa65ee8c682'	System	18 Aug 2020 23:21:15
User entered '18 Aug 2020 18:21'	System	18 Aug 2020 23:21:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 5'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:10:48', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '03078dcd-ba2e-469b-b152-a389428badc4'	System	19 Aug 2020 22:11:15
User entered 'Yes (Y)'	System	19 Aug 2020 22:11:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:10:56', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '03078dcd-ba2e-469b-b152-a389428badc4'	System	19 Aug 2020 22:11:15
User entered '96.6'	System	19 Aug 2020 22:11:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:03', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '03078dcd-ba2e-469b-b152-a389428badc4'	System	19 Aug 2020 22:11:15
User entered 'No (N)'	System	19 Aug 2020 22:11:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:07', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '03078dcd-ba2e-469b-b152-a389428badc4'	System	19 Aug 2020 22:11:15
User entered '19 Aug 2020 17:11'	System	19 Aug 2020 22:11:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 6'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:17', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884'	System	20 Aug 2020 23:30:53
User entered 'Yes (Y)'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:25', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884'	System	20 Aug 2020 23:30:53
User entered '98.4'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884'	System	20 Aug 2020 23:30:53
User entered 'Yes (Y)'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at Day 8 TC ' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 05:58:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at Day 8 TC ' (Site from System).	marissa Mueller (b) (4)	21 Aug 2020 00:55:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:43', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884'	(b) (4)	
User entered '1'	System	20 Aug 2020 23:30:53
	System	20 Aug 2020 23:30:53
	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:43', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884' User entered '0'	System	20 Aug 2020 23:30:53
	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:47', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'f5d1a504-8e3c-4c21-82ef-970fbfad4884'	System	20 Aug 2020 23:30:53
User entered '20 Aug 2020 18:30'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 7'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:08', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	System	22 Aug 2020 02:23:43
User entered 'Yes (Y)'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:18', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	System	22 Aug 2020 02:23:43
User entered '98.6'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:25', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	System	22 Aug 2020 02:23:43
User entered 'Yes (Y)'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will update at Day 8 TC ' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 08:19:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	marissa Mueller (b) (4)	24 Aug 2020 14:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:34', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	(b) (4)	
User entered '1'	System	22 Aug 2020 02:23:43
	System	22 Aug 2020 02:23:43
	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:34', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	System	22 Aug 2020 02:23:43
User entered '0'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:39', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7e189ace-7bff-4126-b1eb-c41d81141f3c'	System	22 Aug 2020 02:23:43
User entered '21 Aug 2020 21:22'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	20 Aug 2020 23:30:53
User entered 'Day 8'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	22 Aug 2020 02:23:43
User entered 'Day 9'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:23', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6d7aed34-72cd-43de-92d9-81f6fa43b8ef'	System	15 Aug 2020 20:45:42
User entered 'None (1)'	System	15 Aug 2020 20:45:42

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:27', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6d7aed34-72cd-43de-92d9-81f6fa43b8ef'	System	15 Aug 2020 20:45:42
User entered 'No (N)'	System	15 Aug 2020 20:45:42

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6d7aed34-72cd-43de-92d9-81f6fa43b8ef'	System	15 Aug 2020 20:45:42
User entered 'No (N)'	System	15 Aug 2020 20:45:42

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:35', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6d7aed34-72cd-43de-92d9-81f6fa43b8ef'	System	15 Aug 2020 20:45:42
User entered 'None (1)'	System	15 Aug 2020 20:45:42

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:39', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6d7aed34-72cd-43de-92d9-81f6fa43b8ef'	System	15 Aug 2020 20:45:42
User entered '15 Aug 2020 15:45'	System	15 Aug 2020 20:45:42

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 15:25'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 17:55'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 18:50'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 2'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:42', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c620521d-7387-4995-8bbb-c6cd6ab96e96'	System	16 Aug 2020 23:43:00
User entered 'None (1)'	System	16 Aug 2020 23:43:00

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:47', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c620521d-7387-4995-8bbb-c6cd6ab96e96'	System	16 Aug 2020 23:43:00
User entered 'No (N)'	System	16 Aug 2020 23:43:00

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:49', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c620521d-7387-4995-8bbb-c6cd6ab96e96'	System	16 Aug 2020 23:43:00
User entered 'No (N)'	System	16 Aug 2020 23:43:00

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:51', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c620521d-7387-4995-8bbb-c6cd6ab96e96'	System	16 Aug 2020 23:43:00
User entered 'None (1)'	System	16 Aug 2020 23:43:00

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:55', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c620521d-7387-4995-8bbb-c6cd6ab96e96'	System	16 Aug 2020 23:43:00
User entered '16 Aug 2020 18:42'	System	16 Aug 2020 23:43:00

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 3'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:45', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '27a782fa-a1c7-458c-93c9-04ff8cd457e7'	System	18 Aug 2020 02:49:26
User entered 'None (1)'	System	18 Aug 2020 02:49:26

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:50', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '27a782fa-a1c7-458c-93c9-04ff8cd457e7'	System	18 Aug 2020 02:49:26
User entered 'No (N)'	System	18 Aug 2020 02:49:26

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:53', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '27a782fa-a1c7-458c-93c9-04ff8cd457e7'	System	18 Aug 2020 02:49:26
User entered 'No (N)'	System	18 Aug 2020 02:49:26

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:48:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '27a782fa-a1c7-458c-93c9-04ff8cd457e7'	System	18 Aug 2020 02:49:26
User entered 'None (1)'	System	18 Aug 2020 02:49:26

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:01', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '27a782fa-a1c7-458c-93c9-04ff8cd457e7'	System	18 Aug 2020 02:49:26
User entered '17 Aug 2020 21:49'	System	18 Aug 2020 02:49:26

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 4'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:19', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb03188a-aedc-4ef0-9889-e73b02846744'	System	18 Aug 2020 23:21:43
User entered 'None (1)'	System	18 Aug 2020 23:21:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb03188a-aedc-4ef0-9889-e73b02846744'	System	18 Aug 2020 23:21:43
User entered 'No (N)'	System	18 Aug 2020 23:21:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb03188a-aedc-4ef0-9889-e73b02846744'	System	18 Aug 2020 23:21:43
User entered 'No (N)'	System	18 Aug 2020 23:21:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:36', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb03188a-aedc-4ef0-9889-e73b02846744'	System	18 Aug 2020 23:21:43
User entered 'None (1)'	System	18 Aug 2020 23:21:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb03188a-aedc-4ef0-9889-e73b02846744'	System	18 Aug 2020 23:21:43
User entered '18 Aug 2020 18:21'	System	18 Aug 2020 23:21:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 5'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:17', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1a7596c-f8ba-43a9-bdd4-763350b26631'	System	19 Aug 2020 22:11:43
User entered 'None (1)'	System	19 Aug 2020 22:11:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:21', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1a7596c-f8ba-43a9-bdd4-763350b26631'	System	19 Aug 2020 22:11:43
User entered 'No (N)'	System	19 Aug 2020 22:11:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:24', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1a7596c-f8ba-43a9-bdd4-763350b26631'	System	19 Aug 2020 22:11:43
User entered 'No (N)'	System	19 Aug 2020 22:11:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:30', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1a7596c-f8ba-43a9-bdd4-763350b26631'	System	19 Aug 2020 22:11:43
User entered 'None (1)'	System	19 Aug 2020 22:11:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:33', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'c1a7596c-f8ba-43a9-bdd4-763350b26631'	System	19 Aug 2020 22:11:43
User entered '19 Aug 2020 17:11'	System	19 Aug 2020 22:11:43

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 6'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:30:56', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'b72cd9e0-e353-49c6-8455-c64f822d2cab'	System	20 Aug 2020 23:31:20
User entered 'None (1)'	System	20 Aug 2020 23:31:20

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:02', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'b72cd9e0-e353-49c6-8455-c64f822d2cab'	System	20 Aug 2020 23:31:20
User entered 'No (N)'	System	20 Aug 2020 23:31:20

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:05', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'b72cd9e0-e353-49c6-8455-c64f822d2cab'	System	20 Aug 2020 23:31:20
User entered 'No (N)'	System	20 Aug 2020 23:31:20

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:10', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'b72cd9e0-e353-49c6-8455-c64f822d2cab'	System	20 Aug 2020 23:31:20
User entered 'None (1)'	System	20 Aug 2020 23:31:20

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:15', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'b72cd9e0-e353-49c6-8455-c64f822d2cab'	System	20 Aug 2020 23:31:20
User entered '20 Aug 2020 18:31'	System	20 Aug 2020 23:31:20

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 7'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:46', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '126b73ca-71cf-4a09-b22e-4e155fb166a9'	System	22 Aug 2020 02:23:51
User entered 'None (1)'	System	22 Aug 2020 02:23:51

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:51', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '126b73ca-71cf-4a09-b22e-4e155fb166a9'	System	22 Aug 2020 02:23:51
User entered 'No (N)'	System	22 Aug 2020 02:23:51

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:22:54', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '126b73ca-71cf-4a09-b22e-4e155fb166a9'	System	22 Aug 2020 02:23:51
User entered 'No (N)'	System	22 Aug 2020 02:23:51

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:02', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '126b73ca-71cf-4a09-b22e-4e155fb166a9'	System	22 Aug 2020 02:23:51
User entered 'None (1)'	System	22 Aug 2020 02:23:51

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:05', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '126b73ca-71cf-4a09-b22e-4e155fb166a9'	System	22 Aug 2020 02:23:51
User entered '21 Aug 2020 21:23'	System	22 Aug 2020 02:23:51

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:45', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:48', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:50', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:52', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:55', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:57', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'None (0)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:45:59', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered 'No (N)'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-15T15:46:03', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '3ebfa3fa-a2bb-4cc0-b457-cc3c847d3867'	System	15 Aug 2020 20:46:06
User entered '15 Aug 2020 15:46'	System	15 Aug 2020 20:46:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 15:25'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 17:55'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '15 Aug 2020 18:50'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 2'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:04', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:09', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:13', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:15', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:19', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'None (0)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:22', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered 'No (N)'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-16T18:42:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '7130891c-ae6-4763-8323-7e5ace5a0002'	System	16 Aug 2020 23:42:37
User entered '16 Aug 2020 18:42'	System	16 Aug 2020 23:42:37

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 3'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:08', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:13', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:18', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:20', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:23', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:30', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'None (0)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:39', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered 'No (N)'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-17T21:49:43', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ad87a558-f2c9-4709-a804-e3a3491d05af'	System	18 Aug 2020 02:49:46
User entered '17 Aug 2020 21:49'	System	18 Aug 2020 02:49:46

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 4'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:49', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:52', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:21:59', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:22:07', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:22:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:22:14', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'None (0)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:22:20', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered 'No (N)'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-18T18:22:25', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '312f409c-e78e-45e5-a67b-90db74353e14'	System	18 Aug 2020 23:22:29
User entered '18 Aug 2020 18:22'	System	18 Aug 2020 23:22:29

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 5'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'None (0)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:47', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'None (0)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:52', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'None (0)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:11:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'None (0)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:12:01', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'None (0)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:12:24', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'No interference with activity (1)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:12:29', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered 'No (N)'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-19T17:12:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'abfc930c-3b02-404d-86c5-1f047bdea13e'	System	20 Aug 2020 23:30:06
User entered '19 Aug 2020 17:12'	System	20 Aug 2020 23:30:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 6'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:21', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'None (0)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'None (0)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'None (0)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:46', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'No interference with activity (1)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:50', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'None (0)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:31:55', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'No interference with activity (1)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:32:02', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered 'No (N)'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-20T18:32:06', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9907a504-a5c7-49fb-85e3-8e9e691d168b'	System	20 Aug 2020 23:32:13
User entered '20 Aug 2020 18:32'	System	20 Aug 2020 23:32:13

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 7'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:12', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:15', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:17', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:19', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:22', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:24', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'None (0)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered 'No (N)'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-08-21T21:23:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '8941e859-1847-4439-9d75-f865c3d84d4c'	System	26 Aug 2020 00:07:06
User entered '21 Aug 2020 21:23'	System	26 Aug 2020 00:07:06

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	20 Aug 2020 23:30:53
User entered 'Day 8'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 23:30:53

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	22 Aug 2020 02:23:43
User entered 'Day 9'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:23:43

US3062265

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:23:43

US3062265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 19:06:32

US3062265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '25 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 19:06:32

US3062265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	26 Aug 2020 19:06:32

US3062265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 19:06:32

US3062265

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 19:05:46

US3062265

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	26 Aug 2020 19:05:46

US3062265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Brianna Burton (b) (4)	31 Aug 2020 21:57:48

US3062265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '31 Aug 2020'	Brianna Burton (b) (4)	31 Aug 2020 21:57:48

US3062265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Contact Made (CONTACT MADE)'	Brianna Burton (b) (4)	31 Aug 2020 21:57:48

US3062265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) Brianna Burton (b) (4)	31 Aug 2020 21:57:48

US3062265

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Brianna Burton (b) (4)	31 Aug 2020 21:57:58

US3062265

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	31 Aug 2020 21:57:58

US3062265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	05 Sep 2020 18:29:48

US3062265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '5 Sep 2020'	Colton King (b) (4)	05 Sep 2020 18:29:48

US3062265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	05 Sep 2020 18:29:48

US3062265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	05 Sep 2020 18:29:48

US3062265

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	05 Sep 2020 18:29:52

US3062265

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	05 Sep 2020 18:29:52

US3062265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Sep 2020 21:02:18

US3062265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 07:15:50
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirming date is correct as entered' (Site from System).	Sherry Henning (b) (4)	23 Sep 2020 21:02:40
	(b) (4)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 21:02:18
User entered '23 Sep 2020'	Sherry Henning (b) (4)	23 Sep 2020 21:02:18
	(b) (4)	

US3062265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	23 Sep 2020 21:02:18

US3062265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'VISIT2'	System	23 Sep 2020 21:02:18

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23 Sep 2020'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14:12'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '23 Sep 2020 14:12'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '97.9' F	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Oral (Oral)'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '99'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '90'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '66'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23 Sep 2020'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '16:27'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '23 Sep 2020 16:27'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '99.1' F	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Oral (Oral)'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '94'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '138'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '94'	Colton King (b) (4)	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Sep 2020 21:49:30

US3062265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Sep 2020 21:03:16

US3062265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23 Sep 2020'	Sherry Henning (b) (4)	23 Sep 2020 21:03:16

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23 Sep 2020'	Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '15:55'	Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '23 Sep 2020 15:55'	System	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'ONCE'	System	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 21:03:43

US3062265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Sep 2020 21:04:31

US3062265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:08:01
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'The lab report for this has been received from the lab and is filed in source, so it appears that GCL did receive this sample.' (Site from DM).	Sherry Henning (b) (4)	09 Oct 2020 15:07:01
	(b) (4)	
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:24:52
User entered '23 Sep 2020'	Sherry Henning (b) (4)	23 Sep 2020 21:04:31
	(b) (4)	

US3062265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '14:45'	Sherry Henning (b) (4)	23 Sep 2020 21:04:31

US3062265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '23 Sep 2020 14:45'	System	23 Sep 2020 21:04:31

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:01:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23 Sep 2020'	Sherry Henning (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '14:48'	Sherry Henning (b) (4)	23 Sep 2020 21:04:50
	(b) (4)	

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '23 Sep 2020 14:48'	System	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	Sherry Henning (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	Sherry Henning (b) (4)	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered empty.	System	23 Sep 2020 21:04:50

US3062265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Sep 2020 21:04:58

US3062265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '1'	System	23 Sep 2020 21:04:58

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:30:38', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5caf2428-c043-415f-83a8-6ec0e78cc752'	System	23 Sep 2020 21:31:07
User entered 'Yes (Y)'	System	23 Sep 2020 21:31:07

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:30:53', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5caf2428-c043-415f-83a8-6ec0e78cc752'	System	23 Sep 2020 21:31:07
User entered '99.1'	System	23 Sep 2020 21:31:07

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:30:59', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5caf2428-c043-415f-83a8-6ec0e78cc752'	System	23 Sep 2020 21:31:07
User entered 'No (N)'	System	23 Sep 2020 21:31:07

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:04', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5caf2428-c043-415f-83a8-6ec0e78cc752'	System	23 Sep 2020 21:31:07
User entered '23 Sep 2020 16:31'	System	23 Sep 2020 21:31:07

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 16:15'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 18:45'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 19:40'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 2'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:08', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ab806cc2-fcc0-434d-b1d8-058204e58002'	System	25 Sep 2020 13:49:47
User entered 'Yes (Y)'	System	25 Sep 2020 13:49:47

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ab806cc2-fcc0-434d-b1d8-058204e58002'	System	25 Sep 2020 13:49:47
User entered '98.6'	System	25 Sep 2020 13:49:47

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:32', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ab806cc2-fcc0-434d-b1d8-058204e58002'	System	25 Sep 2020 13:49:47
User entered 'No (N)'	System	25 Sep 2020 13:49:47

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'ab806cc2-fcc0-434d-b1d8-058204e58002'	System	25 Sep 2020 13:49:47
User entered '25 Sep 2020 08:49'	System	25 Sep 2020 13:49:47

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 3'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 4'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 5'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:00', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	System	28 Sep 2020 13:40:37
User entered 'Yes (Y)'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:12', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	System	28 Sep 2020 13:40:37
User entered '98.6'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:21', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	System	28 Sep 2020 13:40:37
User entered 'Yes (Y)'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'previously reported medications' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 08:40:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	marissa Mueller (b) (4)	28 Sep 2020 16:38:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	(b) (4)	
User entered '1'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	System	28 Sep 2020 13:40:37
User entered '0'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:33', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '2f412f60-7c49-40bc-93f1-ec3aa2721d7a'	System	28 Sep 2020 13:40:37
User entered '28 Sep 2020 08:40'	System	28 Sep 2020 13:40:37

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 6'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:02', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '683e0d38-6ebc-4e35-bbab-2d81f9b6f3c7'	System	29 Sep 2020 03:39:44
User entered 'Yes (Y)'	System	29 Sep 2020 03:39:44

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:22', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '683e0d38-6ebc-4e35-bbab-2d81f9b6f3c7'	System	29 Sep 2020 03:39:44
User entered '98.8'	System	29 Sep 2020 03:39:44

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '683e0d38-6ebc-4e35-bbab-2d81f9b6f3c7'	System	29 Sep 2020 03:39:44
User entered 'No (N)'	System	29 Sep 2020 03:39:44

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:36', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '683e0d38-6ebc-4e35-bbab-2d81f9b6f3c7'	System	29 Sep 2020 03:39:44
User entered '28 Sep 2020 22:39'	System	29 Sep 2020 03:39:44

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 7'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:09:55', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '07579724-e2f4-4540-8505-a398c1697acd'	System	30 Sep 2020 13:10:41
User entered 'Yes (Y)'	System	30 Sep 2020 13:10:41

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:07', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '07579724-e2f4-4540-8505-a398c1697acd'	System	30 Sep 2020 13:10:41
User entered '97.6'	System	30 Sep 2020 13:10:41

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '07579724-e2f4-4540-8505-a398c1697acd'	System	30 Sep 2020 13:10:41
User entered 'No (N)'	System	30 Sep 2020 13:10:41

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:16', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '07579724-e2f4-4540-8505-a398c1697acd'	System	30 Sep 2020 13:10:41
User entered '30 Sep 2020 08:10'	System	30 Sep 2020 13:10:41

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:12', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '282c1167-8dee-48d0-821d-463f84f7a2a2'	System	23 Sep 2020 21:31:29
User entered 'None (1)'	System	23 Sep 2020 21:31:29

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:16', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '282c1167-8dee-48d0-821d-463f84f7a2a2'	System	23 Sep 2020 21:31:29
User entered 'No (N)'	System	23 Sep 2020 21:31:29

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:20', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '282c1167-8dee-48d0-821d-463f84f7a2a2'	System	23 Sep 2020 21:31:29
User entered 'No (N)'	System	23 Sep 2020 21:31:29

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:23', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '282c1167-8dee-48d0-821d-463f84f7a2a2'	System	23 Sep 2020 21:31:29
User entered 'None (1)'	System	23 Sep 2020 21:31:29

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '282c1167-8dee-48d0-821d-463f84f7a2a2'	System	23 Sep 2020 21:31:29
User entered '23 Sep 2020 16:31'	System	23 Sep 2020 21:31:29

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 16:15'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 18:45'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 19:40'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 2'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:52', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '08b1fb86-8237-494c-aad7-cc4a0b215ae0'	System	28 Sep 2020 13:39:51
User entered 'None (1)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:56', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '08b1fb86-8237-494c-aad7-cc4a0b215ae0'	System	28 Sep 2020 13:39:51
User entered 'No (N)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:49:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '08b1fb86-8237-494c-aad7-cc4a0b215ae0'	System	28 Sep 2020 13:39:51
User entered 'No (N)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:01', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '08b1fb86-8237-494c-aad7-cc4a0b215ae0'	System	28 Sep 2020 13:39:51
User entered 'None (1)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:08', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '08b1fb86-8237-494c-aad7-cc4a0b215ae0'	System	28 Sep 2020 13:39:51
User entered '25 Sep 2020 08:50'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 3'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 4'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 5'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:42', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '510564a6-7983-4b13-a46c-e7f412c16ffb'	System	28 Sep 2020 13:41:08
User entered 'None (1)'	System	28 Sep 2020 13:41:08

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:47', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '510564a6-7983-4b13-a46c-e7f412c16ffb'	System	28 Sep 2020 13:41:08
User entered 'No (N)'	System	28 Sep 2020 13:41:08

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:53', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '510564a6-7983-4b13-a46c-e7f412c16ffb'	System	28 Sep 2020 13:41:08
User entered 'No (N)'	System	28 Sep 2020 13:41:08

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:40:59', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '510564a6-7983-4b13-a46c-e7f412c16ffb'	System	28 Sep 2020 13:41:08
User entered 'None (1)'	System	28 Sep 2020 13:41:08

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:01', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '510564a6-7983-4b13-a46c-e7f412c16ffb'	System	28 Sep 2020 13:41:08
User entered '28 Sep 2020 08:41'	System	28 Sep 2020 13:41:08

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 6'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:49', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '0aa9d051-589d-44f0-9896-2a38ba61c0f4'	System	29 Sep 2020 03:40:12
User entered 'None (1)'	System	29 Sep 2020 03:40:12

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:54', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '0aa9d051-589d-44f0-9896-2a38ba61c0f4'	System	29 Sep 2020 03:40:12
User entered 'No (N)'	System	29 Sep 2020 03:40:12

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:39:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '0aa9d051-589d-44f0-9896-2a38ba61c0f4'	System	29 Sep 2020 03:40:12
User entered 'No (N)'	System	29 Sep 2020 03:40:12

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:02', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '0aa9d051-589d-44f0-9896-2a38ba61c0f4'	System	29 Sep 2020 03:40:12
User entered 'None (1)'	System	29 Sep 2020 03:40:12

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:07', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '0aa9d051-589d-44f0-9896-2a38ba61c0f4'	System	29 Sep 2020 03:40:12
User entered '28 Sep 2020 22:40'	System	29 Sep 2020 03:40:12

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 7'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5c898b87-b66e-471c-8c88-d09a34dcb7f8'	System	30 Sep 2020 13:10:55
User entered 'None (1)'	System	30 Sep 2020 13:10:55

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:30', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5c898b87-b66e-471c-8c88-d09a34dcb7f8'	System	30 Sep 2020 13:10:55
User entered 'No (N)'	System	30 Sep 2020 13:10:55

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:37', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5c898b87-b66e-471c-8c88-d09a34dcb7f8'	System	30 Sep 2020 13:10:55
User entered 'No (N)'	System	30 Sep 2020 13:10:55

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5c898b87-b66e-471c-8c88-d09a34dcb7f8'	System	30 Sep 2020 13:10:55
User entered 'None (1)'	System	30 Sep 2020 13:10:55

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:42', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '5c898b87-b66e-471c-8c88-d09a34dcb7f8'	System	30 Sep 2020 13:10:55
User entered '30 Sep 2020 08:10'	System	30 Sep 2020 13:10:55

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:33', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:36', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:38', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:43', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:45', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'None (0)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:47', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered 'No (N)'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-23T16:31:53', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '9595acae-faa6-4b06-a0d5-06bd1dc80985'	System	23 Sep 2020 21:31:58
User entered '23 Sep 2020 16:31'	System	23 Sep 2020 21:31:58

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 16:15'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 18:45'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '23 Sep 2020 19:40'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 2'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:17', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:21', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:24', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:26', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'None (0)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:37', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered 'No (N)'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-25T08:50:41', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '66f077f5-b27e-4609-881d-90c49369fe85'	System	28 Sep 2020 13:39:51
User entered '25 Sep 2020 08:50'	System	28 Sep 2020 13:39:51

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 3'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 4'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 5'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:09', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:11', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:14', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:16', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:19', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:21', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'None (0)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:27', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered 'No (N)'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T08:41:29', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '6dc9e5c6-a9f8-427d-bb42-ccba813bd6be'	System	28 Sep 2020 13:41:35
User entered '28 Sep 2020 08:41'	System	28 Sep 2020 13:41:35

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 6'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:15', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:19', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:22', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:25', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:28', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:30', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'None (0)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:33', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered 'No (N)'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-28T22:40:37', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'a16937e4-61c5-489d-ad39-68d7f2697492'	System	29 Sep 2020 03:40:43
User entered '28 Sep 2020 22:40'	System	29 Sep 2020 03:40:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	23 Sep 2020 21:03:43
User entered 'Day 7'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:49', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:51', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:53', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:56', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:10:58', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:11:01', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'None (0)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:11:06', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered 'No (N)'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-09-30T08:11:09', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'cb90dc9f-51f1-45a5-98c5-a8c229d4b648'	System	30 Sep 2020 13:11:14
User entered '30 Sep 2020 08:11'	System	30 Sep 2020 13:11:14

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 21:03:43

US3062265

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 21:03:43

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Oct 2020 14:49:10

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per CDM, re-query: Please note that since contact was not made, it would be more appropriate to record the Date of Contact Attempt. In the Safety Call Day 43 folder 08 Oct is already recorded as "Contact Made". Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:14:36
Query 'Per CDM, re-query: Please note that since contact was not made, it would be more appropriate to record the Date of Contact Attempt. In the Safety Call Day 43 folder 08 Oct is already recorded as "Contact Made". Please update as appropriate.' answered with 'Final attempt 02OCT2020 added per query' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 21:04:36
User entered '2 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	14 Oct 2020 21:04:17
User opened query 'Per CDM, re-query: Please note that since contact was not made, it would be more appropriate to record the Date of Contact Attempt. In the Safety Call Day 43 folder 08 Oct is already recorded as "Contact Made". Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:56:22
User closed query 'Per CDM, re-query: Please review and verify the date when the contact was attempted. Safety Call Day 43 is recorded for the same date and contact was made. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:56:22
Query 'Per CDM, re-query: Please review and verify the date when the contact was attempted. Safety Call Day 43 is recorded for the same date and contact was made. Thank you. ' answered with 'contact not made. line is labeled contact or contact attempt' (Site from DM).	marissa Mueller (b) (4)	13 Oct 2020 01:17:38

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 12:54:38
User opened query 'Per CDM, re-query: Please review and verify the date when the contact was attempted. Safety Call Day 43 is recorded for the same date and contact was made. Thank you. (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:54:36
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct as entered. Unable to contact subject. Protocol deviation has been written.' (Site from System).	Sherry Henning (b) (4) (b) (4)	09 Oct 2020 14:51:51
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 14:49:10
User entered '8 Oct 2020'	Sherry Henning (b) (4) (b) (4)	09 Oct 2020 14:49:10

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Sherry Henning (b) (4)	09 Oct 2020 14:49:10
	(b) (4)	

US3062265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'unable to contact subject after multiple attempts. Protocol deviation has been written.'	Sherry Henning (b) (4)	09 Oct 2020 14:49:10
	(b) (4)	

US3062265

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Oct 2020 14:50:25

US3062265

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	09 Oct 2020 14:50:25

US3062265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Oct 2020 14:52:05
	(b) (4)	

US3062265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '8 Oct 2020'	Sherry Henning (b) (4)	09 Oct 2020 14:52:05
	(b) (4)	

US3062265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	09 Oct 2020 14:52:05

US3062265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	09 Oct 2020 14:52:05
	(b) (4)	

US3062265

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	12 Oct 2020 23:38:25
	(b) (4)	

US3062265

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	12 Oct 2020 23:38:25

US3062265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:25:59
	(b) (4)	

US3062265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 21:55:40
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	marissa Mueller (b) (4)	23 Oct 2020 14:26:05
answered with 'deviation routing' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Oct 2020 14:25:59
User entered '19 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:25:59
	(b) (4)	

US3062265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:25:59
	(b) (4)	

US3062265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:25:59
	(b) (4)	

US3062265

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:26:09
	(b) (4)	

US3062265

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered 'I'	System	23 Oct 2020 14:26:09

US3062265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:26:45
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '22 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:26:45
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[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 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Clinic (Clinic)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:26:45
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'VISIT3'	System	23 Oct 2020 14:26:45

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '22 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '11:11'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '22 Oct 2020 11:11'	System	23 Oct 2020 14:27:06

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '97.6' F	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '95'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'bpm'	System	23 Oct 2020 14:27:06

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '18'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'breaths/min'	System	23 Oct 2020 14:27:06

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '105'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Oct 2020 14:27:06

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '69'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:27:06
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered 'mmHg'	System	23 Oct 2020 14:27:06

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22

US3062265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22

US3062265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:29:26
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:29:26

US3062265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:29:34
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '22 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:29:34
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '11:38'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:29:34
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '22 Oct 2020 11:38'	System	23 Oct 2020 14:29:34

US3062265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	23 Oct 2020 14:29:39
	(b) (4)	

US3062265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:22
User entered '1'	System	23 Oct 2020 14:29:39

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 64'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '15 Oct 2020 00:01'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '19 Oct 2020 23:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 71'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-10-22T11:44:51', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'd1946267-a602-4080-aa31-f447e6fd1e26'	System	22 Oct 2020 16:45:02
User entered 'No (N)'	System	22 Oct 2020 16:45:02

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-10-22T11:44:48', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'd1946267-a602-4080-aa31-f447e6fd1e26'	System	22 Oct 2020 16:45:02
User entered 'No (N)'	System	22 Oct 2020 16:45:02

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f05775a916e4beb0)', Time: '2020-10-22T11:44:55', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: 'd1946267-a602-4080-aa31-f447e6fd1e26'	System	22 Oct 2020 16:45:02
User entered '22 Oct 2020 11:44:55'	System	22 Oct 2020 16:45:02

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '22 Oct 2020 00:01'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '26 Oct 2020 23:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 78'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1a6eef91ce48e45)', Time: '2020-10-29T13:24:25', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1644a186-59fe-4853-9d74-a1c2d7ff1338'	System	29 Oct 2020 18:24:48
User entered 'No (N)'	System	29 Oct 2020 18:24:48

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1a6eef91ce48e45)', Time: '2020-10-29T13:24:31', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1644a186-59fe-4853-9d74-a1c2d7ff1338'	System	29 Oct 2020 18:24:48
User entered 'No (N)'	System	29 Oct 2020 18:24:48

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1a6eef91ce48e45)', Time: '2020-10-29T13:24:40', User OID: 'PatientReportedOutcome (US3062265)', ODM File OID: '1644a186-59fe-4853-9d74-a1c2d7ff1338'	System	29 Oct 2020 18:24:48
User entered '29 Oct 2020 13:24:40'	System	29 Oct 2020 18:24:48

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '29 Oct 2020 00:01'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '02 Nov 2020 23:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 92'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '12 Nov 2020 00:01'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '16 Nov 2020 23:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered 'Day 99'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Please 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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '19 Nov 2020 00:01'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:36:21
Data entry locked.	System	15 Aug 2020 20:10:47
User entered '23 Nov 2020 23:59'	System	15 Aug 2020 20:10:47

US3062265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	16 Dec 2020 17:50:15
	(b) (4)	

US3062265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) marissa Mueller (b) (4)	16 Dec 2020 17:50:15
	(b) (4)	

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered empty.	(b) (4) marissa Mueller (b) (4)	16 Dec 2020 17:50:15
	(b) (4)	

US3062265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'subject withdrawn prior to call'	(b) (4) marissa Mueller (b) (4)	16 Dec 2020 17:50:15
	(b) (4)	

US3062265

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	16 Dec 2020 17:50:41
	(b) (4)	

US3062265

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	16 Dec 2020 17:50:41

US3062265

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:01:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:59:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry Henning (b) (4)	24 Sep 2020 20:54:40
	(b) (4)	
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 15:43:56
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:11:15
Reviewed for Safety.		25 Sep 2020 12:15:49
User entered 'USA-US090-2020-mRNA-1273-P301000002'	System	25 Sep 2020 12:15:42
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 12:15:42

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:31
Data point term sent to Coder	System	08 Nov 2020 13:29:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:44
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:01:20
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:22:45
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:22:45
Data point term sent to Coder	System	24 Sep 2020 21:00:56
User entered 'Worsening of Alcohol Abuse'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:25
User entered 'Yes (Y)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:01:29
User entered 'No (N)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:01:33
User entered 'No (N)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:01:37
User entered '17 Sep 2020'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:39
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	System	24 Sep 2020 21:00:00

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:01:41
User entered 'No (N)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:42
User entered '23 Sep 2020'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:45
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	System	24 Sep 2020 21:00:00

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Grade 4 (Grade 4)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:47
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Sep 2020 21:34:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Sep 2020 21:00:00
User entered 'Yes (Y)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:02:04
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:02:08
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:02:06
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)	25 Sep 2020 09:59:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	24 Sep 2020 21:34:54
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Sep 2020 21:34:28
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:34:28
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User closed query 'please verify start date of 17Sep2020 per hospital record in source' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:27:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:27:22
Query 'please verify start date of 17Sep2020 per hospital record in source' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	23 Oct 2020 17:20:33
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	23 Oct 2020 17:20:30
	(b) (4)	
User entered '17 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 17:20:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User opened query 'please verify start date of 17Sep2020 per hospital record in source' (Site from CRA).		21 Oct 2020 19:12:51
DataPoint Un-verified.		21 Oct 2020 19:11:46
DataPoint Verified.		21 Oct 2020 16:02:12
User entered '19 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:34:28
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:30:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
Query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' answered with 'Correct as entered' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 18:42:36
User opened query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:57:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:02:14
User entered '23 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:34:28
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:13:00
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:34:57
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:02:25
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:02:27
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:02:29
User entered 'None (NONE)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:03:36
User entered 'I'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:03:37
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:03:40
User entered '0'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 16:03:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:03:44
User entered empty.	Sherry Henning (b) (4)	24 Sep 2020 21:00:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:30:19
User closed query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:30:17
User closed query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' (Site from Safety).		10 Nov 2020 15:30:14
DataPoint Verified.		10 Nov 2020 13:14:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
Query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' answered with 'No withdrawal symptoms recorded on medical records. No symptoms reported by subject during this hospitalization' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 19:07:09
Query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 19:06:14
Query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' answered with 'correct as entered' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 18:43:21
User opened query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	(3736 06 Nov 2020 13:56:37
User opened query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' (Site from Safety).		(3736 06 Nov 2020 13:53:13
User opened query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' (Site from Safety).		(3736 06 Nov 2020 13:51:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 13:25:22
User closed query 'PV Query: Was there any trigger for alcohol abuse episode? Please leave query open until information is available.' (Site from Safety).		27 Oct 2020 13:25:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).		27 Oct 2020 13:25:18
Query 'PV Query: Was there any trigger for alcohol abuse episode? Please leave query open until information is available.' answered with 'Information provided' (Site from Safety).	Jeri King (b) (4)	26 Oct 2020 20:35:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' answered with 'Information provided' (Site from Safety).	Jeri King (b) (4)	26 Oct 2020 20:35:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' answered with 'Information provided' (Site from Safety).	Jeri King (b) (4)	26 Oct 2020 20:35:01
DataPoint Un-verified.	Jeri King (b) (4)	26 Oct 2020 20:34:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IN FOR DAY 29 VISIT. DURING VISIT, SUBJECT REPORTS THAT HE WAS RELEAS ED FROM "REHAB" THIS MORNING. AFTER DISCUSSION WITH SUBJECT, IT APPEARS THAT THE SUBJECT HAD BEEN HOSPITALIZED FOR DETOX. SUBJECT REPORTED THE ALCOHOL ABUSE HAD BEEN A PROBLEM SINCE 6/15/2020 AND DECIDED TO GO TO THE EMERGENCY ROOM ON 9/17/2020. EPIP SUBMITTED AND SUBJECT ALLOWED TO CONTINUE IN STUDY. RELEASE OF RECORDS SIGNED BY SUBJECT FOR EMERGENCY ROOM VISIT AND DETOX CENTER. SUBJECT REPORTS THAT HE WAS NOT GIVEN ANY NEW MEDICATIONS. 10/26/2020 Records received from substance abuse center. In records, it is noted that subject's triggers for alcohol use daily are physical pain and morning withdrawal symptoms. Subject had attended treatment for alcohol abuse in the past. The longest period of sobriety is reported to be 6 years. During hospitalization and treatment center admission, subject was not given any medications to treat the alcohol abuse. Subject was discharged to his private home on 9/23/2020 with plans to follow up with a local outpatient treatment center.' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:34:53
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:26:07
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' answered with 'No COVID testing done during hospital admission' (Site from Safety).	Jeri King (b) (4)	23 Oct 2020 17:44:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was there any trigger for alcohol abuse episode? Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 10:43:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).		08 Oct 2020 10:43:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).		08 Oct 2020 10:43:27
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).		08 Oct 2020 10:43:20
User closed query 'PV Query: Was there any trigger for alcohol abuse episode?' (Site from Safety).		05 Oct 2020 13:58:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		05 Oct 2020 13:56:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		05 Oct 2020 13:56:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:56:05
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:23:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:23:24
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 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:23:20
Query 'PV Query: Was there any trigger for alcohol abuse episode?' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:23:16
User opened query 'PV Query: Was there any trigger for alcohol abuse episode?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:40:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:39:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		02 Oct 2020 18:37:14
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).		02 Oct 2020 18:37:02
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:34:28
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:34:28
User entered 'Subject in for Day 29 visit. During visit, subject reports that he was released from "rehab" this morning. After discussion with subject, it appears that the subject had been hospitalized for detox. Subject reported the alcohol abuse had been a problem since 6/15/2020 and decided to go to the Emergency Room on 9/17/2020. ePIP submitted and subject allowed to continue in study. Release of records signed by subject for Emergency Room visit and detox center. Subject reports that he was not given any new medications.' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:34:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:00:00
User entered empty.	Sherry Henning (b) (4) (b) (4)	24 Sep 2020 21:00:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1'	System	24 Sep 2020 21:00:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1'	System	24 Sep 2020 21:00:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	System	24 Sep 2020 21:34:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.		08 Nov 2020 13:24:07
Reviewed for Safety.		26 Oct 2020 14:15:54
User entered 'USA-US090-2020-mRNA-1273-P301000006'		26 Oct 2020 14:15:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
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: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 04:18:54
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 04:18:54
Data point term sent to Coder	System	08 Nov 2020 13:29:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:44
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		08 Nov 2020 13:24:05
Data point term sent to Coder	System	06 Nov 2020 21:44:49
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	06 Nov 2020 21:44:01
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'updated' (Site from System).	Jeri King (b) (4)	06 Nov 2020 21:44:01
Coding entries removed.	Jeri King (b) (4)	06 Nov 2020 21:43:53
User entered 'CHEST PAIN - musculoskeletal' reason for change: Data Entry Error	Jeri King (b) (4)	06 Nov 2020 21:43:53
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 19:16:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4)	25 Oct 2020 16:45:39
	(b) (4), (b) (6)	21 Oct 2020 18:35:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:30:30
Data point term sent to Coder	System	20 Oct 2020 21:29:54
User entered 'chest pain'	marissa Mueller (b) (4) (b) (4)	20 Oct 2020 21:29:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4)	21 Oct 2020 18:35:27
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 18:35:30
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:35:32
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:14:14
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:29:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '14 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:29:37

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 4 (Grade 4)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
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).		23 Oct 2020 11:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject remains hospitalized. See other AE for details. ' (Site from System).	Jeri King (b) (4)	20 Oct 2020 21:36:10
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	20 Oct 2020 21:29:37
User entered '1'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:03:22
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:03:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:26:44
DataPoint Un-verified.	Jeri King (b) (4)	21 Nov 2020 14:38:00
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	21 Nov 2020 14:38:00
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'Per CRA, the diagnostic procedures needed to be added to EDC. Will update per query. ' (Site from DM).	Jeri King (b) (4)	21 Nov 2020 14:37:36
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:37:40
User closed query 'please verify EKG per hosp note dated 13Oct in source' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:43:02
DataPoint Verified.		10 Nov 2020 13:14:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
Query 'please verify EKG per hosp note dated 13Oct in source' answered with 'updated' (Site from CRA).	Jeri King (b) (4)	23 Oct 2020 17:43:41
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	23 Oct 2020 17:43:29

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'please verify EKG per hosp note dated 13Oct in source' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:54:31
		21 Oct 2020 19:53:56
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:29:37
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:03:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD ACUTE ALCOHOL INTOXICATION AND FELL AT HOME. HE WAS TAKEN TO THE EMERGENCY ROOM FOR THE INJURIES SUSTAINED IN THE FALL. WHILE SUBJECT WAS BEING CARED FOR IN THE EMERGENCY ROOM, HE BEGAN TO HAVE CHEST PAIN. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR OBSERVATION DUE TO CHEST PAIN. ON 10/13/2020, SUBJECT HAD SERIAL TROPONINS DRAWN. ALL WERE NEGATIVE. HE ALSO HAD A CHEST X-RAY. THE RESULTS OF THE CXR WAS "NO ACUTE CARDIOPULMONARY PROCESS". SUBJECT HAD 2 EKGS WHILE IN THE EMERGENCY ROOM. THE FIRST EKG WAS SINUS RHYTHM NO STEMI. THE SECOND EKG WAS SINUS TACHYCARDIA NO STEMI. A NUMBER OF CT SCANS WERE PERFORMED WHILE SUBJECT WAS IN THE MERGENCY ROOM DUE TO THE FALL. SUBJECT HAD CT OF HEAD, C-SPINE, LUMBAR SPINE, THORACIC SPINE, ABDOMEN/PELVIS. NO SIGNIFICANT FINDINGS RELATED TO THE CHEST PAIN WERE DIAGNOSED FROM THE CT SCANS. SUBJECT ALSO HAD A NEGATIVE3 DRUG SCREEN FOR ILLICIT DRUGS. THE CHEST PAIN HAD ENDED WHILE SUBJECT WAS STILL IN THE EMERGENCY ROOM. THE SUBJECT REMAINED IN THE HOSPITAL OVERNIGHT TO OBSERVE DUE TO CHEST PAIN. Subject was discharged from the hospital in stable condition on 10/20/2020. Conmeds were updated per medical records. See SAE of Alcohol Withdrawal symptoms to explain recovered date vs. discharge date.' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:03:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject had acute alcohol intoxication and fell at home. He was taken to the emergency room for the injuries sustained in the fall. While subject was being cared for in the emergency room, he began to have chest pain. Subject was admitted to the hospital for observation due to chest pain. On 10/13/2020, subject had serial troponins drawn. All were negative. He also had a Chest X-Ray. The results of the CXR was "no acute cardiopulmonary process". Subject had 2 EKGs while in the emergency room. The first EKG was sinus rhythm No STEMI. The second EKG was sinus tachycardia No STEMI. A number of CT scans were performed while subject was in the emergency room due to the fall. Subject had CT of head, C-Spine, Lumbar Spine, Thoracic Spine, Abdomen/Pelvis. No significant findings related to the chest pain were diagnosed from the CT scans. Subject also had a negative3 drug screen for illicit drugs. The chest pain had ended while subject was still in the emergency room. The subject remained in the hospital overnight to observe due to chest pain.'	marissa Mueller (b) (4) (b) (4)	20 Oct 2020 21:29:37

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Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:29:37

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Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:29:37

US3062265

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:29:37

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Eye injuries NEC, PT: Periorbital haemorrhage, LLT: Periorbital ecchymosis - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:33
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:29:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:41
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Eye injuries NEC, PT: Periorbital haemorrhage, LLT: Periorbital ecchymosis - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:24:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:24:34
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:30:55
User entered 'left periorbital ecchymosis'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:30:21

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:30:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 21:30:29
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Oct 2020 21:30:29
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 21:30:21
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:30:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:30:21

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Folder: Adverse Events

Form: Adverse Events (3)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:30:21

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:34:46
User entered	System	21 Oct 2020 19:34:38
'USA-US090-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 19:34:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcoholic withdrawal symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:33
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:29:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:41
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:30:54
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcoholic withdrawal symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:42:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:42:32
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:36:08
User entered 'Alcohol Withdrawal Symptoms'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:33:51
User entered 'Yes (Y)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:00
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:35:56
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 13:51:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:35:53
User entered '14 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:35:51
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 13:51:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Yes (Y)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 13:51:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Oct 2020 14:01:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Oct 2020 14:01:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Oct 2020 14:01:00
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:35:39
User entered 'Grade 4 (Grade 4)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:35:42
User entered 'Yes (Y)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
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).		23 Oct 2020 11:49:35
DataPoint Verified.		21 Oct 2020 19:38:33
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 'pt has not been discharged at this time' (Site from System).	marissa Mueller (b) (4)	20 Oct 2020 21:38:45
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Oct 2020 21:35:18
User entered '1'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:16
User entered '13 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:40:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' (Site from Safety).		06 Nov 2020 15:37:02
Query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	05 Nov 2020 14:59:32
DataPoint Un-verified.	Jeri King (b) (4)	05 Nov 2020 14:59:26
User entered '20 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:59:26
User opened query 'PV Query: Please confirm discharge date for event of alcohol withdrawal symptoms and add to EDC.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:13:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:28
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:30
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:32
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:40:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:40:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Oct 2020 21:40:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:35:18
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:40
User entered 'I'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:40:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:01:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 14:01:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:51:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:51:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Oct 2020 21:51:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:35:18
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Only relevant lab test was alcohol level already included.	(b) (4), (b) (6)	16 Dec 2020 16:01:31
' (Site from Safety).		
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Only relevant lab test was alcohol level already included.	Jeri King (b) (4)	15 Dec 2020 21:50:50
' (Site from Safety).		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 20:49:06
User closed query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:13:06
User closed query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' (Site from Safety).		09 Nov 2020 15:13:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		08 Nov 2020 13:24:52
Query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 21:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED FOR OBSERVATION FOR CHEST PAIN ON 10/13/2020. AT THE TIME OF ADMISSION, SUBJECT HAD ACUTE ALCOHOL INTOXICATION. SUBJECT REPORTED THAT HE HAS A HISTORY OF ALCOHOL WITHDRAWAL SEIZURES. SUBJECT WAS CHANGED TO INPATIENT STATUS DUE TO ALCOHOL WITHDRAWAL SYMPTOMS. SUBJECT'S ALCOHOL LEVEL UPON ADMISSION TO THE EMERGENCY ROOM ON 10/13/2020 WAS 404. SUBJECT WAS GIVEN FLUIDS AND MONITORED FOR SYMPTOMS OF ALCOHOL WITHDRAWAL. ON 10/20/2020, SUBJECT REMAINS HOSPITALIZED. WAS GIVEN ATIVAN DURING HOSPITALIZATION DUE TO CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT SCORES. AWAITING RECORDS TO GIVE FURTHER DETAILS. UPDATED START DATE PER MEDICAL RECORDS. SUBJECT WAS DISCHARGED FROM THE HOSPITAL IN STABLE CONDITION ON 10/20/2020. CONMEDS WERE UPDATED PER MEDICAL RECORDS Update 11/6/2020 Per hospital records, subject's withdrawal symptoms were tremors, headache, nausea, vomiting, anxiety and diarrhea. CIWA scale utilized to manage withdrawal symptoms while hospitalized' reason for change: Data Entry Error	Jeri King (b) (4)	06 Nov 2020 21:45:29
Query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	06 Nov 2020 18:44:36
User closed query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:37:06
Query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' answered with 'updated as was a typo' (Site from Safety).	Jeri King (b) (4)	05 Nov 2020 15:00:47

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide symptoms of alcohol withdrawal experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:12:15
User opened query 'PV Query: Please clarify vitamin V1. If incorrect, please update with correct vitamin.' (Site from Safety).		30 Oct 2020 13:11:51
User opened query 'PV Query: Please add alcohol withdrawal seizures to MH eCRF as per narrative, subject reported a history of.' (Site from Safety).		30 Oct 2020 13:11:35
DataPoint Un-verified.	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
User entered 'SUBJECT WAS ADMITTED FOR OBSERVATION FOR CHEST PAIN ON 10/13/2020. AT THE TIME OF ADMISSION, SUBJECT HAD ACUTE ALCOHOL INTOXICATION. SUBJECT REPORTED THAT HE HAS A HISTORY OF ALCOHOL WITHDRAWAL SEIZURES. SUBJECT WAS CHANGED TO INPATIENT STATUS DUE TO ALCOHOL WITHDRAWAL SYMPTOMS. SUBJECT'S ALCOHOL LEVEL UPON ADMISSION TO THE EMERGENCY ROOM ON 10/13/2020 WAS 404. SUBJECT WAS GIVEN FLUIDS AND MONITORED FOR SYMPTOMS OF ALCOHOL WITHDRAWAL. ON 10/20/2020, SUBJECT REMAINS HOSPITALIZED. WAS GIVEN ATIVAN DURING HOSPITALIZATION DUE TO CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT SCORES. AWAITING RECORDS TO GIVE FURTHER DETAILS.	marissa Mueller (b) (4)	23 Oct 2020 14:01:00
	(b) (4)	
Updated start date per medical records. Subject was discharged from the hospital in stable condition on 10/20/2020. Conmeds were updated per medical records' reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:36:54

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was admitted for observation for chest pain on 10/13/2020. At the time of admission, subject had acute alcohol intoxication. Subject reported that he has a history of alcohol withdrawal seizures. Subject was changed to inpatient status due to alcohol withdrawal symptoms. Subject's alcohol level upon admission to the emergency room on 10/13/2020 was 404. Subject was given fluids and monitored for symptoms of alcohol withdrawal. On 10/20/2020, subject remains hospitalized. Was given Ativan during hospitalization due to Clinical Institute Withdrawal Assessment scores. Awaiting records to give further details.'	Jeri King (b) (4)	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
Data point term sent to Coder	System	08 Nov 2020 13:29:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:41
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminitis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:42:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:42:28
Data point term sent to Coder	System	20 Oct 2020 21:41:17
User entered 'transaminitis'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:50:35
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:54:13
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	10 Nov 2020 15:35:40
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	10 Nov 2020 15:35:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	10 Nov 2020 15:35:35
	(b) (4)	
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:35:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:41:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:45
DataPoint Un-verified.		21 Oct 2020 19:38:42
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:40:51
DataPoint Un-verified.		21 Oct 2020 19:38:53
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:40:50
DataPoint Un-verified.		21 Oct 2020 19:38:57
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:41:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:41:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:41:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:31
Data point term sent to Coder	System	08 Nov 2020 13:29:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:46
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:43:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:43:31
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:42:18
User entered 'hypokalemia'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:41:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:41:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:41:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:41:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:41:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:37
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:29:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:44:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:44:32
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:43:21
User entered 'hyperglycemia'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:42:23

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:33
Data point term sent to Coder	System	08 Nov 2020 13:29:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:44
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:44:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:44:33
Data point term sent to Coder	System	20 Oct 2020 21:43:23
User entered 'vertigo'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:42:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:42:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'l'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:42:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:42:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:24:54
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'This is an acute diagnosis. Not a worsening.' (Site from DM).	Jeri King (b) (4)	21 Nov 2020 14:38:48
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:35:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Poisoning and toxicity, PT: Alcohol poisoning, LLT: Alcohol intoxication acute - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:35
Data point term sent to Coder	System	08 Nov 2020 13:29:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:44
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Poisoning and toxicity, PT: Alcohol poisoning, LLT: Alcohol intoxication acute - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:56:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Oct 2020 21:56:37
User: (b) (6) version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:44:27
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:44:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '14 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:44:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 4 (Grade 4)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		23 Oct 2020 11:50:03
DataPoint Verified.		21 Oct 2020 19:38:33
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.'	marissa Mueller (b) (4)	20 Oct 2020 21:44:32
answered with 'per protocol grade 4 as was seen in ER' (Site from System).	(b) (4)	
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		20 Oct 2020 21:44:09
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:49:07
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 21:52:36
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:52:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:15:57
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:36:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '1'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:52:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:16:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:44:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:44:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:44:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Please note this AE overlaps with AE#29 & 30. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 15:36:39
Query 'Per DM CLR: Please note this AE overlaps with AE#29 & 30. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'correct per hospital records' (Site from DM).	marissa Mueller (b) (4)	12 Jan 2021 23:57:00
User opened query 'Per DM CLR: Please note this AE overlaps with AE#29 & 30. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:08:25
User closed query 'please verify L side abdominal pain as per 13Oct hosp note' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:41:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
Data point term sent to Coder	System	08 Nov 2020 13:29:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
Query 'please verify L side abdominal pain as per 13Oct hosp note' answered with 'correct as entered' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:16:57
User opened query 'please verify L side abdominal pain as per 13Oct hosp note' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:21:05

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Folder: Adverse Events

Form: Adverse Events (10)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:46:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:46:22
Data point term sent to Coder	System	20 Oct 2020 21:45:29
User entered 'generalized pain'	marissa Mueller (b) (4) (b) (4)	20 Oct 2020 21:45:12

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:45:12

US3062265

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 15:36:56
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'subject was withdrawn from study' (Site from DM).	marissa Mueller (b) (4)	12 Jan 2021 23:56:11
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:08:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:45:12

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:48:32
DataPoint Un-verified.	Jeri King (b) (4)	21 Nov 2020 14:39:33
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	21 Nov 2020 14:39:33
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'Per CRA, diagnostic procedures were to be entered. Deleted per query. ' (Site from DM).	Jeri King (b) (4)	21 Nov 2020 14:39:24
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:38:03
User closed query 'please add entry for back pain (much worse than usual" per 13Oct hosp note' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:43:43
User closed query 'please verify C-spine CT as per 13Oct hosp note.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:43:41
User closed query 'please verify L hip xray per hosp note dated 13Oct in source' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:43:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:16:09
Query 'please verify C-spine CT as per 13Oct hosp note.' answered with 'see procedures page' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 15:16:05
Query 'please verify L hip xray per hosp note dated 13Oct in source' answered with 'see procedures pag' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 15:15:59
Query 'please add entry for back pain (much worse than usual" per 13Oct hosp note' answered with 'Back Pain covered under the generalized pain due to the fall.	Jeri King (b) (4)	24 Oct 2020 14:40:35
No further AE required' (Site from CRA).	(b) (4), (b) (6)	
User opened query 'please add entry for back pain (much worse than usual" per 13Oct hosp note' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:11:42
User opened query 'please verify C-spine CT as per 13Oct hosp note.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:09:19
User opened query 'please verify L hip xray per hosp note dated 13Oct in source' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 19:52:20
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:51:55
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:45:12

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:45:12

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'please add Fall per source' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:42:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Eye injuries NEC, PT: Periorbital haematoma, LLT: Periorbital hematoma - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:34
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:29:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
Query 'please add Fall per source' answered with 'fall not found in AE log of source. events that occurred due to fall are documented as AEs' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:18:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User opened query 'please add Fall per source' (Site from CRA).		21 Oct 2020 19:17:01
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Eye injuries NEC, PT: Periorbital haematoma, LLT: Periorbital hematoma - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:24:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:24:34
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:46:29
User entered 'left periorbital hematoma'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:45:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 15:37:11
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'subject was withdrawn from study' (Site from DM).	marissa Mueller (b) (4)	12 Jan 2021 23:57:26
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:08:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:45:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:45:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:45:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Oct 2020 21:45:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:45:51
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 21:56:35
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Un-verified.	Jeri King (b) (4)	24 Oct 2020 15:16:44
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:16:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '1'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:12:27
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'All therapeutic procedures removed' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 21:56:53
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 21:56:35
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:56:35
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:43:00
User closed query 'please verify CT of head as per hospital note date 13Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:42:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:16:44
Query 'please verify CT of head as per hospital note date 13Oct2020.' answered with 'see procedures page' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 15:16:36

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'please verify CT of head as per hospital note date 13Oct2020.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:47:50
		21 Oct 2020 19:46:56
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:45:51
	(b) (4)	

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:45:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:45:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Scalp laceration - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
Data point term sent to Coder	System	08 Nov 2020 13:29:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder		08 Nov 2020 13:28:46
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Scalp laceration - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 23:38:26
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 23:38:26
Data point term sent to Coder	System	20 Oct 2020 21:47:32
User entered 'scalp abrasions'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:46:56

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:46:56

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:46:56
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:46:56

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Folder: Adverse Events

Form: Adverse Events (12)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:46:56

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:34
Data point term sent to Coder	System	08 Nov 2020 13:29:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User closed query 'please consider adding nausea as accompanied AE' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 13:26:32
Query 'please consider adding nausea as accompanied AE' answered with 'to be updated' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:18:35
User opened query 'please consider adding nausea as accompanied AE' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:36:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:49:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:49:27
Data point term sent to Coder	System	20 Oct 2020 21:48:33
User entered 'vomiting'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '14 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:47:58

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Folder: Adverse Events

Form: Adverse Events (13)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '14 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:47:58

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'l'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:47:58
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:47:58

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:47:58

US3062265

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Nov 2020 13:46:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:46:30
Data point term sent to Coder	System	08 Nov 2020 13:29:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:50:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:50:20
Data point term sent to Coder	System	20 Oct 2020 21:49:35
User entered 'left elbow fracture'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:44:59
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:44:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '14 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:48:36

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 15:37:25
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'subject was withdrawn from study' (Site from DM).	marissa Mueller (b) (4)	12 Jan 2021 23:57:44
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:09:09
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:48:36

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 21:57:16
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:57:16
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:45:16
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Un-verified.	Jeri King (b) (4)	24 Oct 2020 15:17:40
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:17:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered '1'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:12:07
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 21:57:16
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:57:16
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'All therapeutic procedures removed' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 21:57:09
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:40:43
User closed query 'please verify CT of elbow as per hosp note of 13Oct' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 14:45:19
DataPoint Verified.		08 Nov 2020 14:45:12
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:17:40
Query 'please verify CT of elbow as per hosp note of 13Oct' answered with 'see procedures page' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 15:17:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'please verify CT of elbow as per hosp note of 13Oct' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 20:30:24
		21 Oct 2020 20:29:59
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:48:36
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:48:36

US3062265

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	20 Oct 2020 21:48:36

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
Data point term sent to Coder	System	08 Nov 2020 13:29:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:50:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:50:20
Data point term sent to Coder	System	20 Oct 2020 21:49:36
User entered 'thrombocytopenia'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '13 Oct 2020'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:49:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	20 Oct 2020 21:49:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'No (N)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered 'I'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered '0'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
DataPoint Verified.		21 Oct 2020 19:38:33
User entered empty.	marissa Mueller (b) (4)	20 Oct 2020 21:49:12
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	20 Oct 2020 21:49:12

US3062265

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	System	20 Oct 2020 21:49:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Nov 2020 13:30:30
Data point term sent to Coder	System	08 Nov 2020 13:30:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 13:57:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	23 Oct 2020 13:57:35
Data point term sent to Coder	System	23 Oct 2020 13:56:41
User entered 'chronic sinusitis'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:43
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:55:59

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:54
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:55:59

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:45:59
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:32
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:40
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:46:53
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:55:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	23 Oct 2020 13:55:59

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	23 Oct 2020 13:55:59

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (18)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:45:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Nov 2020 13:45:30
Data point term sent to Coder	System	08 Nov 2020 13:30:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:02:36
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:02:36
Data point term sent to Coder	System	23 Oct 2020 13:57:42
User entered 'degenerative spondylosis'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:18
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:56:45

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:31
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:56:45

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

US3062265

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:37
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:39
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:43
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:47
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:47:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:07
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	23 Oct 2020 13:56:45

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	23 Oct 2020 13:56:45

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: OA hip - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 23:51:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 23:51:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 12:48:42
Data point term sent to Coder	System	08 Nov 2020 13:30:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
Data point term sent to Coder	System	23 Oct 2020 13:57:42
User entered 'right hip degenerative changes'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:45
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:57:15

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:53
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:58
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:48:56
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:57:15

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:00
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:04
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:06
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:18
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:24
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:26
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:35
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:40
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:49:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:57:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	23 Oct 2020 13:57:15

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Folder: Adverse Events

Form: Adverse Events (19)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	23 Oct 2020 13:57:15

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (20)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:36
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:30:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 13:59:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 13:59:30
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 13:58:43
User entered 'wheezing'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:07
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:11
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:58:03

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:17
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	23 Oct 2020 13:58:03

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:21
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:34
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:38
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:45
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:49
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:54
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:50:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:51:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:51:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:51:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 13:58:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	System	23 Oct 2020 13:58:03

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Folder: Adverse Events

Form: Adverse Events (20)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	23 Oct 2020 13:58:03

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:12:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:25
User entered 'USA-US090-2020-mRNA-1273-P301000009'	System	10 Nov 2020 20:14:19
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 20:14:19
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (21)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:17
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcoholic withdrawal symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:31
Data point term sent to Coder	System	08 Nov 2020 13:30:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcoholic withdrawal symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:50:44
Data point term sent to Coder	System	29 Oct 2020 14:02:13
User entered 'Alcohol Withdrawal Symptoms'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:14
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 14:01:25

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:14:13
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '02 Nov 2020' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:14:13
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Grade 4 (Grade 4)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:48
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
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).		02 Nov 2020 19:46:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject remains hospitalized at this time. ' (Site from System).	Jeri King (b) (4)	29 Oct 2020 14:01:46
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 Oct 2020 14:01:25
User entered '1'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Form: Adverse Events (21)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '02 Nov 2020' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:14:13
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:52:59
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:01
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:12
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:14
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 14:01:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 14:01:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	29 Oct 2020 14:01:59
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 14:01:25
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:19
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:23
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:14:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:53:25
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: SAE Narrative = HE STATED HE STRUCK HIS HEAD. COMPLAINTS OF PAIN IN NECK AND RIGHT LOWER QUADRANT UPON ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:39:57
User closed query 'Per DM CLR: SAE Narrative = ALCOHOL LEVEL WAS 450. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:39:38
User closed query 'Per DM CLR: SAE Narrative = FALLING ON THE ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:39:24
Query 'Per DM CLR: SAE Narrative = HE STATED HE STRUCK HIS HEAD. COMPLAINTS OF PAIN IN NECK AND RIGHT LOWER QUADRANT UPON ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'generalized pain previously reported' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:46:57
Query 'Per DM CLR: SAE Narrative = ALCOHOL LEVEL WAS 450. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'no procedure performed. This was based on a lab test' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:46:21

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = FALLING ON THE ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'falling in itself is not an AE. The result of the fall is considered an AE. correct as entered' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:45:39
User opened query 'Per DM CLR: SAE Narrative = HE STATED HE STRUCK HIS HEAD. COMPLAINTS OF PAIN IN NECK AND RIGHT LOWER QUADRANT UPON ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: SAE Narrative = ALCOHOL LEVEL WAS 450. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:42:18
User opened query 'Per DM CLR: SAE Narrative = FALLING ON THE ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		23 Jan 2021 06:42:13
User closed query 'PV Query: Please report the signs/symptoms (including vital signs and physical exam findings) experienced by the subject.' (Site from Safety).		23 Jan 2021 06:42:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		07 Jan 2021 14:52:57
Query 'PV Query: Please report the signs/symptoms (including vital signs and physical exam findings) experienced by the subject.' answered with 'See update.' (Site from Safety).	Riley King (b) (4)	07 Jan 2021 14:52:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'See update.' (Site from Safety).	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:08:34
	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:08:27
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	06 Jan 2021 16:08:13

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Form: Adverse Events (21)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 10/28/2020, SUBJECT CALLED THE SITE TO REPORT THAT HE WAS HOSPITALIZED AGAIN. SUBJECT REPORTS THAT HE WAS BROUGHT TO THE EMERGENCY ROOM BY EMS AFTER FALLING ON THE ICE WHILE INTOXICATED. SUBJECT WAS EVALUATED IN THE EMERGENCY ROOM. WAS ADMITTED TO THE HOSPITAL FOR OBSERVATION FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT PROTOCOL IMPLEMENTED FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. AN ALCOHOL LEVEL INDICATED THAT SUBJECT'S ALCOHOL LEVEL WAS 450 WHILE IN THE EMERGENCY ROOM. RECORDS TO BE COLLECTED FROM HOSPITAL AFTER SUBJECT IS DISMISSED. ACCORDING TO SUBJECT, PLAN TO DISCHARGE POTENTIALLY ON 10/29/2020. SUBJECT WAS TAKEN TO THE EMERGENCY ROOM ON 10/27/2020 AFTER FALLING WHILE INTOXICATED. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR ALCOHOL WITHDRAWAL SYMPTOMS. HE RECEIVED SERAX AND ATIVAN FOR THE WITHDRAWAL SYMPTOMS BASED ON THE CIWA SCORING SYSTEM. SUBJECT REMAINED HOSPITALIZED THROUGH 11/2/2020. HE WAS DISCHARGED HOME. PER HOSPITAL RECORDS, SUBJECT PLANS TO STAY WITH A FRIEND UNTIL HE IS ABLE TO ATTEND INPATIENT REHABILITATION. SUBJECT WAS DISCHARGED IN STABLE CONDITION. Per hospital records, subject reports falling outside of his home. He stated he struck his head. Complaints of pain in neck, mid back, low back, and right lower quadrant upon admission. Subject appeared intoxicated on admission. Subject's alcohol level was 450 mg/dL with a reference range of <10 mg/dL. Vital signs	Riley King (b) (4)	06 Jan 2021 16:08:13

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[Narrative](#)

Audit	User	Time (GMT)
on admission were as follows: temperature 97.8 F, pulse rate 100 bpm, respiratory rate 16 breaths per minute, blood pressure 115/74 mmHg, and 98% O2 saturation. Subject requested to be admitted to the hospital for detox and placement for alcoholism. Subject appeared stable and resting comfortably upon admission. No signs of trauma noted. Subject stated fractures found were old fractures. Subject dismissed on 11/02/2020 and planned to stay with a friend until accepted into inpatient rehab.' reason for change: Data Entry Error		
User opened query 'PV Query: Please report the signs/symptoms (including vital signs and physical exam findings) experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 22:27:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		17 Nov 2020 22:26:50
DataPoint Verified.		10 Nov 2020 12:53:34
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 10/28/2020, SUBJECT CALLED THE SITE TO REPORT THAT HE WAS HOSPITALIZED AGAIN. SUBJECT REPORTS THAT HE WAS BROUGHT TO THE EMERGENCY ROOM BY EMS AFTER FALLING ON THE ICE WHILE INTOXICATED. SUBJECT WAS EVALUATED IN THE EMERGENCY ROOM. WAS ADMITTED TO THE HOSPITAL FOR OBSERVATION FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT PROTOCOL IMPLEMENTED FOR ALCOHOL WITHDRAWAL SYMPTOM MANAGEMENT. AN ALCOHOL LEVEL INDICATED THAT SUBJECT'S ALCOHOL LEVEL WAS 450 WHILE IN THE EMERGENCY ROOM. RECORDS TO BE COLLECTED FROM HOSPITAL AFTER SUBJECT IS DISMISSED. ACCORDING TO SUBJECT, PLAN TO DISCHARGE POTENTIALLY ON 10/29/2020. Subject was taken to the Emergency room on 10/27/2020 after falling while intoxicated. subject was admitted to the hospital for alcohol withdrawal symptoms. He received Serax and Ativan for the withdrawal symptoms based on the CIWA scoring system. Subject remained hospitalized through 11/2/2020. He was discharged home. Per hospital records, subject plans to stay with a friend until he is able to attend inpatient rehabilitation. Subject was discharged in stable condition.' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:14:13

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'On 10/28/2020, subject called the site to report that he was hospitalized again. Subject reports that he was brought to the emergency room by EMS after falling on the ice while intoxicated. Subject was evaluated in the emergency room. Was admitted to the hospital for observation for alcohol withdrawal symptom management. Clinical Institute Withdrawal Assessment protocol implemented for alcohol withdrawal symptom management. An alcohol level indicated that subject's alcohol level was 450 while in the emergency room. Records to be collected from hospital after subject is dismissed. According to subject, plan to discharge potentially on 10/29/2020.'	Jeri King (b) (4)	29 Oct 2020 14:01:25

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	29 Oct 2020 14:01:25

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	29 Oct 2020 14:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	29 Oct 2020 14:01:25

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Thoracic vertebral fracture, LLT: Thoracic vertebral fracture - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:38
Data point term sent to Coder	System	08 Nov 2020 13:30:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Thoracic vertebral fracture, LLT: Thoracic vertebral fracture - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 13:13:50
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 13:13:50
Data point term sent to Coder	System	29 Oct 2020 16:06:25
User entered 'T11 and T12 end plate fracture'	Jeri King (b) (4)	29 Oct 2020 16:05:52

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Oct 2020 16:06:13
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	29 Oct 2020 16:06:13
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		29 Oct 2020 16:05:52
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:23
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:32
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:36
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:53
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jeri King (b) (4)	29 Oct 2020 16:06:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	29 Oct 2020 16:05:52

US3062265

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:09:57
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'This is an acute problem and not worsening of MH condition.' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 22:32:38
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Alcohol Abuse. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:36:33
DataPoint Verified.		10 Nov 2020 12:57:36
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Poisoning and toxicity, PT: Alcohol poisoning, LLT: Alcohol intoxication acute - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:30
Data point term sent to Coder	System	08 Nov 2020 13:30:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Poisoning and toxicity, PT: Alcohol poisoning, LLT: Alcohol intoxication acute - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 16:38:42

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Oct 2020 16:38:42
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 16:07:27
User entered 'Acute Alcohol Intoxication'	Jeri King (b) (4)	29 Oct 2020 16:07:07

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:38
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:40
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	29 Oct 2020 16:07:07

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	29 Oct 2020 16:07:07

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

US3062265

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:09
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:11
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:16
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:24
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:26
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:58:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:42:30
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 22:33:54
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		15 Dec 2020 22:33:48
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 22:33:48
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 22:33:48
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Dec 2020 22:33:40
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:36:59
DataPoint Verified.		10 Nov 2020 12:59:07
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Oct 2020 16:07:17
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	29 Oct 2020 16:07:17

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User entered '0'	System	29 Oct 2020 16:07:07
	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Un-verified.	(b) (4) Jeri King (b) (4)	15 Dec 2020 22:33:40
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 22:33:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:02:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:19:29
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:36:03
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:42:38
DataPoint Un-verified.	Riley King (b) (4)	06 Jan 2021 16:25:35
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:25:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:02:16
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:02:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:02:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:02:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	29 Oct 2020 16:07:07

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Clavicle fracture, LLT: Clavicle fracture - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:34
	(b) (4)	
Data point term sent to Coder	System	08 Nov 2020 13:30:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Clavicle fracture, LLT: Clavicle fracture - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:45:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:45:19
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 14:19:45
User entered 'right distal 3rd clavicle fracture'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:17
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:21
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:25
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:27
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:19:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:19:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:19:33
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:29
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:38
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:40
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:43
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:48
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:03:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:01
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:16
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

US3062265

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:43
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:32
Data point term sent to Coder	System	08 Nov 2020 13:30:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:21:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:21:18
Data point term sent to Coder	System	05 Nov 2020 14:20:46
User entered 'hyponatremia'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:47
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:54
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:58
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:37
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 13:51:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:52:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 13:51:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:05:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

US3062265

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:20:30

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:20:30

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Folder: Adverse Events

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:20:30

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Phosphorus metabolism disorders, PT: Hypophosphataemia, LLT: Hypophosphatemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:37
Data point term sent to Coder	System	08 Nov 2020 13:30:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Phosphorus metabolism disorders, PT: Hypophosphataemia, LLT: Hypophosphatemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:22:18
Data point term sent to Coder	System	05 Nov 2020 14:21:47
User entered 'hypophosphatemia'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:28
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:32
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:37
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '29 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:21:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:21:27
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:21:27
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:21:23
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:54
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:59
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Un-verified.	(b) (4) Jeri King (b) (4)	15 Dec 2020 22:35:41
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 22:35:41
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:22
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:44:31
DataPoint Un-verified.	Jeri King (b) (4)	15 Dec 2020 22:35:47
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 22:35:41
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:40:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '1'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	05 Nov 2020 14:21:23

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Folder: Adverse Events

Form: Adverse Events (27)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:21:27

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:21:23

US3062265

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:54
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:38
Data point term sent to Coder	System	08 Nov 2020 13:30:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:52
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:23:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:23:19
Data point term sent to Coder	System	05 Nov 2020 14:22:47
User entered 'urinary retention'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:58
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:59
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:01
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:03
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:05
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:07
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:09
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:17
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:22
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:24
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:29
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:31
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:34
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:36
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:38
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:40
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:44
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:49
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:54
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:56
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:58
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:00
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:22:19

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:22:19

US3062265

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:32
Data point term sent to Coder	System	08 Nov 2020 13:30:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:55:19
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:55:19
Data point term sent to Coder	System	05 Nov 2020 14:24:49
User entered 'joint pain, generalized'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:32
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:34
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:36
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:38
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data no required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:39
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:41
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:43
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:25
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:48
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:51
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:53
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:01
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:03
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:07
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:12
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:14
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:16
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:19
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 14:26:27
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:26:27
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 14:23:57
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:21
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:23
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:26
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

US3062265

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:23:57

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:57
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Nov 2020 13:30:32
Data point term sent to Coder	System	08 Nov 2020 13:30:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:52
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:28:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:28:23
Data point term sent to Coder	System	05 Nov 2020 14:27:50
User entered 'back pain'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:55
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:53
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:00
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:02
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:04
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:05
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:08
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:10
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:13
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:17
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:19
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:21
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:22
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:25
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:31
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:33
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:35
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:37
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:39
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:42
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:44
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:46
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:48
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	05 Nov 2020 14:27:32

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:50
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:52
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:27:32

US3062265

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query "" Per MM: please update event term to reflect etiology/ medical diagnosis if known. ' (Site from DM). Query ""	(b) (4), (b) (6)	17 Dec 2020 07:49:59
Per MM: please update event term to reflect etiology/ medical diagnosis if known. ' answered with 'Wheezing is per medical records. ' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 22:36:22
User opened query "" Per MM: please update event term to reflect etiology/ medical diagnosis if known. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:03:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 13:31:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	08 Nov 2020 13:31:32
Data point term sent to Coder	System	08 Nov 2020 13:30:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Nov 2020 13:29:40
Data point term sent to Coder	System	08 Nov 2020 13:28:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Nov 2020 13:28:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:30:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Nov 2020 14:30:34
Data point term sent to Coder	System	05 Nov 2020 14:28:51

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'wheezing'	Jeri King (b) (4) [REDACTED]	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:23
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:25
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:27
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:30
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:32
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:34
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:37
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	System	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:39
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:42
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:47
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:49
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:51
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:54
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:56
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:57
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:12:59
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:01
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:04
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:06
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:10
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:12
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:14
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:16
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:20
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:22
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:24
DataPoint activated with code reason code Data required.	(b) (4)	08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Nov 2020 13:28:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:26
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:28
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '0'	System	05 Nov 2020 14:28:44

US3062265

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14
User entered '1'	System	05 Nov 2020 14:28:44

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
DataPoint activated with code reason code Data required.		08 Nov 2020 13:29:40
DataPoint inactivated with code reason code Data not required.		08 Nov 2020 13:28:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 13:36:22
User closed query 'Per CDM, re-query: Response noted, however there is still no corresponding Conmed recorded that matches the information on the Diary Dose 2, Temperature day, Day 5 (27 Sep). Please also note that there's no record for Safety Call Day 36. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:22:46
Query 'Per CDM, re-query: Response noted, however there is still no corresponding Conmed recorded that matches the information on the Diary Dose 2, Temperature day, Day 5 (27 Sep). Please also note that there's no record for Safety Call Day 36. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Record for Safety call Day 36 has been completed. Information on Diary Dose 2 for Day 5, will be reviewed with subject at next Safety Call (Day 50). eCRF will be updated at that time.' (Site from DM).	Sherry Henning (b) (4)	09 Oct 2020 14:58:10
User opened query 'Per CDM, re-query: Response noted, however there is still no corresponding Conmed recorded that matches the information on the Diary Dose 2, Temperature day, Day 5 (27 Sep). Please also note that there's no record for Safety Call Day 36. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:23:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
User closed query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the medications were previously reported, however there is no matching medication on the ConMed eCRF for the same timepoint. Please note that if the medication is already recorded on the ConMed eCRF, the indication field can be updated to reflect that the medication was given for both the solicited reaction and the medical history condition. Please update the ConMed eCRF as appropriate or provide more information to clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:23:50
Query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the medications were previously reported, however there is no matching medication on the ConMed eCRF for the same timepoint. Please note that if the medication is already recorded on the ConMed eCRF, the indication field can be updated to reflect that the medication was given for both the solicited reaction and the medical history condition. Please update the ConMed eCRF as appropriate or provide more information to clarify. ' answered with 'to be collected at next TC' (Site from DM).	marissa Mueller (b) (4)	30 Sep 2020 19:12:45
User opened query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the medications were previously reported, however there is no matching medication on the ConMed eCRF for the same timepoint. Please note that if the medication is already recorded on the ConMed eCRF, the indication field can be updated to reflect that the medication was given for both the solicited reaction and the medical history condition. Please update the ConMed eCRF as appropriate or provide more information to clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:40:29
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:43:34

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EAB) (1725)

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US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'please verify use of IV Ativan and PPI (proton pump inhibitor) per 13Oct hosp note' (Site from CRA).	(b) (4)	
Query 'please verify use of IV Ativan and PPI (proton pump inhibitor) per 13Oct hosp note' answered with 'to be updated upon receipt of MAR' (Site from CRA).	marissa Mueller (b) (4)	08 Nov 2020 13:39:53
User opened query 'please verify use of IV Ativan and PPI (proton pump inhibitor) per 13Oct hosp note' (Site from CRA).	(b) (4)	22 Oct 2020 23:05:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Aug 2020 20:45:19
Data point term sent to Coder User entered 'Carvedilol'	(b) (4)	
	System	17 Aug 2020 20:45:19
	Colton King (b) (4)	17 Aug 2020 20:44:57
	(b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Hypertension'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered '6.25'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'mg (mg)'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'once daily (QD)'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Oral (ORAL)'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
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)	19 Aug 2020 10:36:52
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 per protocol ' (Site from System).	Colton King (b) (4)	17 Aug 2020 20:46:03
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	17 Aug 2020 20:44:17
User entered 'un Feb 2020'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:44:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:44:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:44:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	17 Aug 2020 20:44:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Please verify use of morphine, Percocet and Toradol per hosp record' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 13:39:40
Query 'Please verify use of morphine, Percocet and Toradol per hosp record' answered with 'to be updated upon receipt of MAR' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:05:49
User opened query 'Please verify use of morphine, Percocet and Toradol per hosp record' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 20:06:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:18:15
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:18:15
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:46:00
User entered 'Pregabalin'	Colton King (b) (4)	17 Aug 2020 20:45:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Right leg Pain'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered '75'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'mg (mg)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:45:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'as needed (PRN)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Oral (ORAL)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:45:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
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)	19 Aug 2020 10:37:02
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 per protocol ' (Site from System).	Colton King (b) (4)	17 Aug 2020 20:45:58
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	17 Aug 2020 20:45:43
User entered '01 Jun 2020'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered '0'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'Yes (Y)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered empty.	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:17
User entered 'No (N)'	Colton King (b) (4)	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	17 Aug 2020 20:45:43

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:01:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:01:32
Data point term sent to Coder	System	05 Nov 2020 14:55:22
User entered 'MORPHINE sulfate' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:54:44
Data point term sent to Coder	System	05 Nov 2020 14:47:15
User entered 'morphine' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:46:38
Data point term sent to Coder	System	23 Oct 2020 14:06:51
User entered 'MS'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:40
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:44
User entered 'generalized pain'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:46
User entered '2'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:47
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:49
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:52
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:54
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:56
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:21:58
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:03
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:05
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:07
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:10
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:12
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:05:53
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:05:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:05:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:05:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:01:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:01:31
Data point term sent to Coder	System	23 Oct 2020 14:06:51
User entered 'ativan'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:23
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:31
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:33
User entered '2'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:35
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:38
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:39
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:42
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:44
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:46
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:48
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:51
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:53
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:55
User entered '18 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:22:57
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:20
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:06:20

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:06:20

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:06:20

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:59:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:59:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:13
Data point term sent to Coder	System	05 Nov 2020 15:00:33
User entered 'VITAMIN B1' reason for change:	Jeri King (b) (4)	05 Nov 2020 15:00:31
Data Entry Error		
Data point term sent to Coder	System	23 Oct 2020 14:06:51
User entered 'vitamin V1'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:11
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:15
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:17
User entered '100'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:19
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:20
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:22
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:24
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:26
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:28
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:30
User entered '17 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:32
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:34
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:36
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:38
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:06:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:06:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:06:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:06:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID, PRODUCTSYNONYM: FOLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:06:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	23 Oct 2020 15:06:39
Data point term sent to Coder	System	23 Oct 2020 14:07:52
User entered 'folate'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:51
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:53
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:55
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:57
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:23:59
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:01
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:03
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:05
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:07
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:09
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:10
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:13
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:15
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:24:17
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:07:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:07:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:07:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Oct 2020 14:08:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Oct 2020 14:08:37
Data point term sent to Coder	System	23 Oct 2020 14:07:53
User entered 'multivitamin'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:07
User entered 'nutritional supplement'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:00
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:09
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:11
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:25
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:14
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:27
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:29
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:31
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:32
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:34
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:37
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:26:39
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:07:50
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:07:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:07:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:07:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:09:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:09:40
Data point term sent to Coder	System	23 Oct 2020 14:08:55
User entered 'carvedilol'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:33
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: For Con Med #8 and 15 - Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:26:36
Query 'Per DM CLR: For Con Med #8 and 15 - Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'natural progression of disease' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:12:12
	(b) (4)	
User opened query 'Per DM CLR: For Con Med #8 and 15 - Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:00:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:35
User entered 'hypertension'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:37
User entered '12.5'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:39
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:40
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:42
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:45
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:47
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:49
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:52
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:54
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:27:55
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:00
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:05
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:08:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	23 Oct 2020 14:08:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:08:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:08:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:26:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:17:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:17:41
Data point term sent to Coder	System	06 Jan 2021 16:16:36
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' answered with 'updated per source.' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:16:03
DataPoint Un-verified.	Riley King (b) (4)	06 Jan 2021 16:15:56
Coding entries removed.	Riley King (b) (4)	06 Jan 2021 16:15:56
User entered 'LIDODERM 5% PATCH' reason for change: Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:15:56
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:00:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:21:38

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	23 Oct 2020 15:21:38
User: (b) (6) version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	23 Oct 2020 14:09:56
User entered 'lidoderm patch'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:19
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:20
User entered 'generalized pain'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:36
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:37
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:28:39
User entered 'patch'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:10
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:12
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:13
User entered 'Topical (TOPICAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:15
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:17
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:19
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:21
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:23
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:26
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:02
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:02

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:02

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:09:02

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:29:34
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:38:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:38:50
Data point term sent to Coder	System	23 Oct 2020 14:09:56
User entered 'protonix'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:04
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:08
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:49
User entered '40'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:14
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:57
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:55
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:53
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:30:51
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:01
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:03
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:05
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:07
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:10
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:31:12
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:27
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:27

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:27

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:09:27

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 14:04:35
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 14:04:35
Data point term sent to Coder	System	23 Oct 2020 14:09:56
User entered 'lovenox'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:29
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:27
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:23
User entered '40'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:21
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:19
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:17
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:15
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:33
User entered 'Subcutaneous (SUBCUTANEOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:40
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:38
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:36
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:42
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:43
User entered '15 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:32:45
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:09:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:09:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:09:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:45
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)	23 Oct 2020 14:11:36
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	23 Oct 2020 14:10:57
User entered 'tylenol'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:47
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:49
User entered 'generalized pain'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:16
User entered '325'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:14
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:12
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:10
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:08
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:33:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:18
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:20
User entered '17 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:22
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:27
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:34:29
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:21
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:21

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:21

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:21

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
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 17:49:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:49:58
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Conmed #13, 16, 17, 19, 20 are given for the AE#9, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:29:46
Query 'Per DM CLR: Conmed #13, 16, 17, 19, 20 are given for the AE#9, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated per source' (Site from DM).	Riley King (b) (4) (b) (4)	06 Jan 2021 16:13:20
User opened query 'Per DM CLR: Conmed #13, 16, 17, 19, 20 are given for the AE#9, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:01:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:06

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
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)	23 Oct 2020 15:18:38
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:38
Data point term sent to Coder	System	23 Oct 2020 14:11:58
User entered 'normal saline' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	23 Oct 2020 14:11:14
User entered 'NS'	marissa Mueller (b) (4) (b) (4)	23 Oct 2020 14:10:59

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:04
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:12
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:14
User entered '1000'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:16
User entered 'mL (mL)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:19
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:20
User entered 'once (ONCE)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:22
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:24
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:02
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:00
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:35:59
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:05
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:06
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:08
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:10:59
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:59

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:59

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:10:59

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:17:41
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:17:41
Data point term sent to Coder	System	06 Jan 2021 16:15:35
Coding entries removed.	Riley King (b) (4)	06 Jan 2021 16:15:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:12:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:12:42
Data point term sent to Coder	System	23 Oct 2020 14:11:59
User entered 'aspirin'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:24
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:34:28
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'updated per AE' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:15:22
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	06 Jan 2021 16:15:11
	(b) (4)	
User entered 'CHEST PAIN - musculoskeletal' reason for change: Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:15:11
	(b) (4)	
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:01:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:26
User entered 'chest pain'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:28
User entered '324'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:29
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:31
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:33
User entered 'once (ONCE)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:35
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:37
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:38
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:41
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:43
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:45
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:47
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:36:50
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:11:51
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:11:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:11:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:11:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: APRESOLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:13:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:13:30
Data point term sent to Coder User entered 'apresoline'	System marissa Mueller (b) (4)	23 Oct 2020 14:13:02 23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:06
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:04
User entered 'hypertension'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:11
User entered '10'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:13
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:15
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:17
User entered 'once (ONCE)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:19
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:21
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:23
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:25
User entered '19 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:28
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:30
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:32
User entered '19 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:34
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:12:15
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:12:15

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 17:46:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	26 Oct 2020 17:46:29
Data point term sent to Coder	System	23 Oct 2020 14:14:04
User entered '1/2 normal saline 20 potassium chloride (20mcg potassium chloride)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:54
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:56
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:37:58
User entered '100'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:00
User entered 'mL (mL)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:03
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:05
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	23 Oct 2020 14:13:42
User entered 'other (OTHER)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Oct 2020 14:13:42
	(b) (4)	
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	23 Oct 2020 14:13:29
User entered 'once daily (QD)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:06
User entered 'every hour'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:08
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:10
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:17
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:15
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:13
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:19
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:38:21
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:13:29
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:13:42
User entered '1'	System	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:13:42
User entered 'I'	System	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:13:42
User entered '804 (804)'	System	23 Oct 2020 14:13:29

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:25
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 17:46:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	26 Oct 2020 17:46:29
Data point term sent to Coder	System	23 Oct 2020 14:15:05
User entered '1/2 NORMAL SALINE 20 POTASSIUM CHLORIDE (20MCG POTASSIUM CHLORIDE)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:27
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:29
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:31
User entered '75'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:33
User entered 'mL (mL)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:35
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:14:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:39
User entered 'other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:37
User entered 'every hour'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:41
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:43
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:45
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:46
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:49
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:51
User entered '14 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:39:53
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL, PRODUCTSYNONYM: SUBLIMAZE [FENTANYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:12:34
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:12:34
Data point term sent to Coder	System	23 Oct 2020 14:15:06
User entered 'sublimaze'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:08
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:09
User entered 'generalized pain'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:11
User entered '50'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:14
User entered 'ug (ug)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:16
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:19
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:22
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:24
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:26
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:28
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:30
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:32
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:34
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:40:36
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:14:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:14:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:21:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	23 Oct 2020 15:21:37
Data point term sent to Coder	System	23 Oct 2020 14:16:09
User entered 'Magnesium'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'g (g)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:15:23
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	23 Oct 2020 14:15:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:15:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:15:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS WITH MINERALS, PRODUCT: VITAMINS WITH MINERALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:05:16
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	23 Nov 2020 07:05:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
Data point term sent to Coder	System	23 Oct 2020 14:17:10
User entered 'vitamin B1 200mg, magnesium 1g, multiple vitamin injection 10mL, D5W 1000mL'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'acute alcohol intoxication'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '1000'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mL (mL)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once (ONCE)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:01

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:58:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:58:42
Data point term sent to Coder DataPoint Un-verified.	System	06 Jan 2021 16:18:37
	Riley King (b) (4)	06 Jan 2021 16:17:48
Coding entries removed.	Riley King (b) (4)	06 Jan 2021 16:17:48
User entered 'VENTOLIN (90 mcg)' reason for change: Data Entry Error DataPoint Verified.	Riley King (b) (4)	06 Jan 2021 16:17:48
	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:18:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:18:46
Data point term sent to Coder User entered 'ventolin'	System	23 Oct 2020 14:18:12
	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'wheezing'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:36:54
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated per conmed. ' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:17:56
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:02:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'puff (PUFF)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:17:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:17:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:14:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:14:33
Data point term sent to Coder	System	23 Oct 2020 14:19:15
User entered 'proventil (2.5mg/3ml)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'wheezing'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'unit'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nebulizer'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:18:34
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:18:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:18:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:18:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: ARFORMOTEROL TARTRATE, PRODUCTSYNONYM: BROVANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:02:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 14:22:23
User entered 'brovana (15mcg/2mL)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'wheezing'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'unit'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nebulizer'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:21:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	23 Oct 2020 14:21:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:21:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:21:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE, PRODUCTSYNONYM: PULMICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:14:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:14:31
Data point term sent to Coder	System	23 Oct 2020 14:23:24
User entered 'pulmicort (0.25mg/2ML)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'wheezing'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'unit'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nebulizer'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '20 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:22:54
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	23 Oct 2020 14:22:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	23 Oct 2020 14:22:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	23 Oct 2020 14:22:54

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:25:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:25:38
Data point term sent to Coder	System	23 Oct 2020 14:24:28
User entered 'zofran'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nausea'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '4'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '19 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:23:40
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:23:40

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:23:40

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:23:40

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
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)	06 Jan 2021 16:54:41
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	06 Jan 2021 16:54:41
Data point term sent to Coder	System	06 Jan 2021 16:22:41
Coding entries removed.	Riley King (b) (4)	06 Jan 2021 16:22:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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)	23 Oct 2020 15:18:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	23 Oct 2020 15:18:08
Data point term sent to Coder	System	23 Oct 2020 14:24:29
User entered 'percocet (5mg/325mg) acetaminophen'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:37:48
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated per source. ' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:22:11
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:22:05
User entered 'GENERALIZED Pain' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:04:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Yes (Y)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:24:14
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:24:14

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-DUR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:59:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:59:24
Data point term sent to Coder	System	23 Oct 2020 14:25:29
User entered 'potassium chloride (K-Dur)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '40'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:33:04
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated per source' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:22:58
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:22:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:22:48
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:04:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'ug (ug)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	06 Jan 2021 16:22:48
	(b) (4)	
User entered 'milliequivalent' reason for change:	Riley King (b) (4)	06 Jan 2021 16:22:48
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '13 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '16 Oct 2020'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	marissa Mueller (b) (4)	23 Oct 2020 14:25:19
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:25:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:25:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	23 Oct 2020 14:25:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 16:23:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 16:23:54
Data point term sent to Coder	System	29 Oct 2020 16:50:56
User entered 'TORADOL'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'GENERALIZED PAIN'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '15' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:34:32
User entered '30'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'please verify as 1Nov2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:47:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:47:46
Query 'please verify as 1Nov2020 as per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	10 Nov 2020 18:09:23
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	10 Nov 2020 18:09:19
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 13:53:32
DataPoint Verified.		10 Nov 2020 13:48:25
User opened query 'please verify as 1Nov2020 as per CM log' (Site from CRA).		10 Nov 2020 13:43:31
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:47:44
User entered '01 Nov 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	10 Nov 2020 18:09:19
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 13:53:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:50:46
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:50:46

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:52:35
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:52:35
Data point term sent to Coder	System	05 Nov 2020 14:34:58
Coding entries removed.	Jeri King (b) (4)	05 Nov 2020 14:34:03
	(b) (4)	
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 13:13:26
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 13:13:26
Data point term sent to Coder	System	29 Oct 2020 16:53:00
User entered 'PANTOPRAZOLE'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:34:03
User entered 'ACUTE ALCOHOL INTOXICATION'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '40'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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). 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	05 Nov 2020 14:34:20
User entered 'once daily (QD)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:34:20
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). User entered 'once (ONCE)'	System	05 Nov 2020 14:34:03
	Janna Martinez (b) (4)	29 Oct 2020 16:51:58
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:51:58
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '30 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:34:03
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:34:20
User entered empty.	System	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:34:20
User entered empty.	System	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:34:20
User entered empty.	System	29 Oct 2020 16:51:58

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User closed query 'Per DM CLR: Conmed # 30, 31, 32 and 37 are given for AE#23, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Conmed # 30, 31, 32 and 37 are given for AE#23, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'correct' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:35:18
User opened query 'Per DM CLR: Conmed # 30, 31, 32 and 37 are given for AE#23, however, "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:25:05
DataPoint Verified.	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	12 Dec 2020 16:05:16
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
Data point term sent to Coder	Coder Import (b) (4)	30 Oct 2020 16:21:55
User entered 'ZOFRAN'	(b) (4)	
	System	29 Oct 2020 16:53:03
	Janna Martinez (b) (4)	29 Oct 2020 16:52:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'ACUTE ALCOHOL INTOXICATION'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '4'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:52:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once (ONCE)'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:52:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:52:49
	(b) (4)	

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 16:54:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 16:54:52
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	29 Oct 2020 16:54:52
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 16:52:49
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	29 Oct 2020 16:52:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 01:41:03
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 01:41:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
Data point term sent to Coder	System	05 Nov 2020 14:32:55
User entered 'D5W 1000mL, vitamin B-1200mg, magnesium 1Gm, multivitamin 10mL'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'acute alcohol intoxication'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '1000'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mL (mL)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once (ONCE)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:32:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
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)	18 Apr 2021 17:49:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	18 Apr 2021 17:49:58
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
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)	05 Nov 2020 14:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:35:21
Data point term sent to Coder	System	05 Nov 2020 14:33:58
User entered 'normal saline'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'acute alcohol intoxication'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '200'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mL (mL)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'other (OTHER)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'every 1 hour'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:33:34

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: OXAZEPAM, PRODUCTSYNONYM: SERAX [OXAZEPAM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Jan 2021 17:09:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Jan 2021 17:09:42
Data point term sent to Coder	System	06 Jan 2021 16:27:45
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	06 Jan 2021 16:27:11
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Riley King (b) (4)	06 Jan 2021 16:27:11
DataPoint Un-verified.	Riley King (b) (4)	06 Jan 2021 16:27:02
User entered 'SERAX (Oxazepam)' reason for change: Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:27:02
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 09:26:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
Data point term sent to Coder	System	05 Nov 2020 14:36:02

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Serax'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '15'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'other (OTHER)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'every 8 hours'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '31 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:35:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID, PRODUCTSYNONYM: FOLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:21
Data point term sent to Coder	System	05 Nov 2020 14:37:02
User entered 'folate'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nutritional supplement'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:36:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:37:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:37:22
Data point term sent to Coder	System	05 Nov 2020 14:37:02
User entered 'multivitamin'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nutritional supplement'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'tablet (TABLET)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:36:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS, PRODUCTSYNONYM: VIT B1 [VITAMIN B1 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:55:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:55:18
Data point term sent to Coder	System	05 Nov 2020 14:38:04
User entered 'VITAMIN B1' reason for change:	Jeri King (b) (4)	05 Nov 2020 14:37:25
Data Entry Error		
User entered 'vitamin B12'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Yes (Y)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nutritional supplement'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '100'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:37:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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)	05 Nov 2020 14:40:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:40:18
Data point term sent to Coder	System	05 Nov 2020 14:39:05
User entered 'lactated ringers'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'acute alcohol intoxication'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '100'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mL (mL)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'other (OTHER)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'every 1 hour'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:38:30

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: ARFORMOTEROL TARTRATE, PRODUCTSYNONYM: BROVANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:41:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:41:21
Data point term sent to Coder	System	05 Nov 2020 14:40:07
User entered 'brovana'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'wheezing'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '15'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'ug (ug)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'twice daily (BID)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'nebulizer'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:39:08

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:43:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:43:20
Data point term sent to Coder	System	05 Nov 2020 14:40:06
User entered 'lidoderm 5% patch'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Other (OTHER)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'patch'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Topical (TOPICAL)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:39:47

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:43:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:43:21
Data point term sent to Coder	System	05 Nov 2020 14:41:08
User entered 'lyrica'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '75'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:40:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:42:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:42:20
Data point term sent to Coder	System	05 Nov 2020 14:41:08
User entered 'protonix'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '40'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:40:50

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:42:21
Data point term sent to Coder	System	05 Nov 2020 14:42:09
User entered 'ativan'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0.5'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '27 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '29 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:41:24

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:44:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	05 Nov 2020 14:44:20
Data point term sent to Coder	System	05 Nov 2020 14:43:10
User entered 'potasium chloride'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'hypokalemia'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '20'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:36:04
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated. ' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:20:04
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:19:59
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	06 Jan 2021 16:19:59
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:05:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'ug (ug)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Un-verified.	(b) (4) Riley King (b) (4)	06 Jan 2021 16:19:59
User entered 'milliequivalents' reason for change:	(b) (4)	
Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'three times daily (TID)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '3'	System	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:42:17

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:44:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:44:18
Data point term sent to Coder	System	05 Nov 2020 14:43:10
User entered 'dilaudid'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'I'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:42:51

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
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)	05 Nov 2020 14:45:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:45:19
Data point term sent to Coder	System	05 Nov 2020 14:44:12
User entered 'tylenol'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '650'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:43:19

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM PHOSPHATE DIBASIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 07:38:07
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:38:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
Data point term sent to Coder	System	05 Nov 2020 14:44:12
User entered 'potassium phosphate'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Un-verified.	(b) (4) Riley King (b) (4)	06 Jan 2021 16:20:42
User entered '500' reason for change: Data Entry Error	(b) (4) Riley King (b) (4)	06 Jan 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '5'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded 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)	13 Jan 2021 11:38:33
Query 'Per DM CLR: Please review the dose recorded 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).	Riley King (b) (4)	06 Jan 2021 16:20:48
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded 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)	12 Dec 2020 16:06:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'four times daily (QID)'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '29 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:44:08
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:44:03
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '4'	System	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:44:03

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:48:22
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:48:22
Data point term sent to Coder	System	05 Nov 2020 14:46:14
User entered 'oxycodone immediate release'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '5'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:45:23

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:36:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:36:27
Data point term sent to Coder	System	05 Nov 2020 14:55:22
User entered 'MORHPHINE sulfate' reason for change: Data Entry Error	Jeri King (b) (4)	05 Nov 2020 14:54:29
Data point term sent to Coder	System	05 Nov 2020 14:48:16
User entered 'morphphine'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'generalized pain'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '2'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'as needed (PRN)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered empty.	System	05 Nov 2020 14:47:18

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:48:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:48:19
Data point term sent to Coder	System	05 Nov 2020 14:48:16
User entered 'lovenox'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '40'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '29 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:47:49

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:20
Data point term sent to Coder	System	05 Nov 2020 14:51:19
User entered 'flomax'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'urinary retention'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0.4'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:51:10

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:37:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:37:23
Data point term sent to Coder	System	05 Nov 2020 14:52:20
User entered 'magnesium oxide'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '400'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'mg (mg)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'twice daily (BID)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Oral (ORAL)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '29 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:51:53

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:30:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:30:21
Data point term sent to Coder	System	05 Nov 2020 14:53:20
User entered 'vitamin B12'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'alcohol withdrawal symptoms'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '1000'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'ug (ug)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'once daily (QD)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'Intramuscular (INTRAMUSCULAR)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '01 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '0'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered '02 Nov 2020'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:48:25
User entered 'No (N)'	Jeri King (b) (4)	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '1'	System	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '804 (804)'	System	05 Nov 2020 14:52:22

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:01:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User closed query 'Per CDM, per DM CLR re-query on AE #11, AE#14: Please note that there were queries which were NOT asking the site to delete the DIAGNOSTIC procedures previously recorded on the Con Proc page. Please review and update the Con Proc page to record all concomitant procedures. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 12:51:12
Query 'Per CDM, per DM CLR re-query on AE #11, AE#14: Please note that there were queries which were NOT asking the site to delete the DIAGNOSTIC procedures previously recorded on the Con Proc page. Please review and update the Con Proc page to record all concomitant procedures. ' answered with 'Added back per query. ' (Site from DM).	Riley King (b) (4)	06 Jan 2021 16:09:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	06 Jan 2021 16:09:02
	(b) (4)	
User opened query 'Per CDM, per DM CLR re-query on AE #11, AE#14: Please note that there were queries which were NOT asking the site to delete the DIAGNOSTIC procedures previously recorded on the Con Proc page. Please review and update the Con Proc page to record all concomitant procedures. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:58:38
Query 'Per CDM, per DM CLR re-query on AE #11, AE#14: Please note that there were queries which were NOT asking the site to delete the DIAGNOSTIC procedures previously recorded on the Con Proc page. Please review and update the Con Proc page to record all concomitant procedures. If Diagnostic, please ensure the Indication selected for the procedure is "Diagnostic". ' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:55:48

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:01:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, per DM CLR re-query on AE #11, AE#14: Please note that there were queries which were NOT asking the site to delete the DIAGNOSTIC procedures previously recorded on the Con Proc page. Please review and update the Con Proc page to record all concomitant procedures. If Diagnostic, please ensure the Indication selected for the procedure is "Diagnostic". ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	18 Dec 2020 13:53:46
	Jeri King (b) (4)	15 Dec 2020 21:56:11
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 21:56:11
User closed query 'please verify EKG, xray of R&L elbow, CT of head, maxillofacial, spine, C-spine, T-spine, lumbar spine per 13oct hosp record' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:35:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:35:28
Query 'please verify EKG, xray of R&L elbow, CT of head, maxillofacial, spine, C-spine, T-spine, lumbar spine per 13oct hosp record' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 22:59:25
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 22:58:23
User opened query 'please verify EKG, xray of R&L elbow, CT of head, maxillofacial, spine, C-spine, T-spine, lumbar spine per 13oct hosp record' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:39:30
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 15:44:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:37
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	marissa Mueller (b) (4)	22 Oct 2020 23:00:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'EKG'	marissa Mueller (b) (4)	22 Oct 2020 23:00:02
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:37
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:13:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 23:13:45
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 23:13:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:00:02
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:02
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:02
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User closed query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #1 EKG (13 OCT 2020). Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review start/end dates of marissa Mueller this Procedure as it overlaps with Procedure #1 EKG (13 OCT 2020). Verify and update start/end dates or remove duplicate entry as necessary. ' answered with 'multiple EKGs on same day per records' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:46:41
User opened query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #1 EKG (13 OCT 2020). Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4)	23 Feb 2021 19:39:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 06:12:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	marissa Mueller (b) (4)	22 Oct 2020 23:00:15
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'EKG'	marissa Mueller (b) (4)	22 Oct 2020 23:00:15
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:42
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:13:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 23:13:58
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 23:13:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:00:15
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:15
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:15
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:45
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	marissa Mueller (b) (4)	22 Oct 2020 23:00:31

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:45
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Chest X-Ray'	marissa Mueller (b) (4)	22 Oct 2020 23:00:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:45
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:14:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 23:14:05
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 23:14:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 23:00:31
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:45
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	marissa Mueller (b) (4)	22 Oct 2020 23:00:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:50
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:10:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:50
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'X-ray Right Elbow'	Jeri King (b) (4)	24 Oct 2020 15:10:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User closed query 'Per DM CLR Re-query: Per response kindly check "diagnostic or other" in the indication field as this was not done for any reported AE else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:40:06
Query 'Per DM CLR Re-query: Per response kindly check "diagnostic or other" in the indication field as this was not done for any reported AE else clarify.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	17 Mar 2021 14:54:46
DataPoint Un-verified.	marissa Mueller (b) (4)	17 Mar 2021 14:54:31
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	marissa Mueller (b) (4)	17 Mar 2021 14:54:31
User opened query 'Per DM CLR Re-query: Per response kindly check "diagnostic or other" in the indication field as this was not done for any reported AE else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 02:04:32
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 02:04:32
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'please, clarify as this was performed during a hospital stay previously reported' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:41:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:15:58
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:50
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:10:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:50
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:10:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:55
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:11:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:55
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT Head without contrast'	Jeri King (b) (4)	24 Oct 2020 15:11:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Jan 2021 16:09:55
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:11:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:09:55
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:11:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:00
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:11:33

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:00
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT Maxillofacial without contrast'	Jeri King (b) (4)	24 Oct 2020 15:11:33

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:11:33

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:00
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:11:33

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:04
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:11:55

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
	(b) (4)	
User entered 'CT Cervical Spine without contrast'	Jeri King (b) (4)	24 Oct 2020 15:11:55

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	(b) (4)	06 Jan 2021 16:10:04
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:11:55

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:04
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:11:55

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:11
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:12:22

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:11
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT Thoracic Spine without contrast'	Jeri King (b) (4)	24 Oct 2020 15:12:22

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:12:22

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:11
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:12:22

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:12:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
	(b) (4)	
User entered 'CT Lumbar spine without contrast'	Jeri King (b) (4)	24 Oct 2020 15:12:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:12:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:25
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:53:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:12:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:13:00

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:30
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'X-ray right hip'	Jeri King (b) (4)	24 Oct 2020 15:13:00

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:30
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:13:00

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:30
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:13:00

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #14 LEFT ELBOW FRACTURE (14 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #14 LEFT ELBOW FRACTURE (14 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'AE date updated' (Site from DM).	marissa Mueller (b) (4)	23 Feb 2021 19:43:59
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #14 LEFT ELBOW FRACTURE (14 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:17:08
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:37
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:13:12

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:37
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT left elbow'	Jeri King (b) (4)	24 Oct 2020 15:13:12

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	(b) (4)	06 Jan 2021 16:10:37
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:13:12

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:13:12

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:13:28

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:41
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT abdomen/pelvis'	Jeri King (b) (4)	24 Oct 2020 15:13:28

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	(b) (4)	06 Jan 2021 16:10:41
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:13:28

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:41
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:13:28

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:45
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '13 Oct 2020'	Jeri King (b) (4)	24 Oct 2020 15:13:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:45
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'X-ray left elbow'	Jeri King (b) (4)	24 Oct 2020 15:13:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	(b) (4)	06 Jan 2021 16:10:45
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	24 Oct 2020 15:13:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:45
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	24 Oct 2020 15:13:42

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:50
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:57:11

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT ABDOMIN/PELVIS'	Janna Martinez (b) (4)	29 Oct 2020 16:57:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Janna Martinez (b) (4)	29 Oct 2020 16:57:11
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:54:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:57:11
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:54
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:57:47

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:54
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT THORACIC SPINE'	Janna Martinez (b) (4)	29 Oct 2020 16:57:47
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:54
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Janna Martinez (b) (4)	29 Oct 2020 16:57:47
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:54
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:57:47
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:58
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '27 Oct 2020'	Janna Martinez (b) (4)	29 Oct 2020 16:58:09

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:58
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'CT HEAD'	Janna Martinez (b) (4)	29 Oct 2020 16:58:09
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:58
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Janna Martinez (b) (4)	29 Oct 2020 16:58:09
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:10:58
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Janna Martinez (b) (4)	29 Oct 2020 16:58:09
	(b) (4)	

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:11:02
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered '28 Oct 2020'	Jeri King (b) (4)	05 Nov 2020 14:25:27

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:11:02
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'foley catheter placement'	Jeri King (b) (4)	05 Nov 2020 14:25:27

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:11:02
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	05 Nov 2020 14:25:27

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	06 Jan 2021 16:11:02
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	15 Dec 2020 21:55:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:42:04
User entered empty.	Jeri King (b) (4)	05 Nov 2020 14:25:27

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered '27 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'CT Cervical spine'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	23 Feb 2021 19:38:16

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered '27 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'X-ray right shoulder'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	23 Feb 2021 19:38:31

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered '27 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:48
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'chest x-ray'	marissa Mueller (b) (4)	23 Feb 2021 19:38:48

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	23 Feb 2021 19:38:48

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:38:48
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:01:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered '13 Oct 2020'	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:39:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:01:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'CT lumbar spine without contrast'	marissa Mueller (b) (4)	23 Feb 2021 19:39:11

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	23 Feb 2021 19:39:11

US3062265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:01:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:44:40
User entered empty.	(b) (4) marissa Mueller (b) (4)	23 Feb 2021 19:39:11
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered '20 Nov 2020'	marissa Mueller (b) (4)	02 Dec 2020 19:52:13
	(b) (4)	

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	marissa Mueller (b) (4)	02 Dec 2020 19:52:13
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered 'inaccurate data and to allow time for subject to get health in order.'	marissa Mueller (b) (4)	02 Dec 2020 19:52:13

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered empty.	marissa Mueller (b) (4)	02 Dec 2020 19:52:13
	(b) (4)	

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered empty.	marissa Mueller (b) (4)	02 Dec 2020 19:52:13

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered empty.	marissa Mueller (b) (4)	02 Dec 2020 19:52:13
	(b) (4)	

US3062265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:59
User entered empty.	marissa Mueller (b) (4)	02 Dec 2020 19:52:13
	(b) (4)	

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'USA-US090-2020-MRNA-1273-P301000002'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'USA-US090-2020-MRNA-1273-P301000002'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
User entered '25/Sep/2020 08:16'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.		05 Oct 2020 13:59:16
User entered 'I'		25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'USA-US090-2020-MRNA-1273-P301000002'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
User entered '05/Oct/2020 09:59'	System	05 Oct 2020 13:59:22

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:27:01
DataPoint Verified.		21 Oct 2020 19:10:31
User entered 'I'		05 Oct 2020 13:59:22

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered	System	25 Sep 2020 12:15:42
'USA-US090-2020-MRNA-1273-P301000002'		

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.		05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:22
User entered '26/Oct/2020 11:27'	System	26 Oct 2020 15:27:10

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:24
Reviewed for Safety.		27 Oct 2020 13:25:38
User entered 'I'		26 Oct 2020 15:27:10

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'USA-US090-2020-MRNA-1273-P301000002'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:41
User entered '27/Oct/2020 09:25'	System	27 Oct 2020 13:25:47

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:43
Reviewed for Safety.		27 Oct 2020 14:17:10
User entered 'I'		27 Oct 2020 13:25:47

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'USA-US090-2020-MRNA-1273-P301000002'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Yes (Y)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'No (N)'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Richard'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Glover'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '700 Medical Center Dr.'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'Newton'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered 'KS'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:16:25
User entered '67114'	System	25 Sep 2020 12:15:42

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:10:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:59:16
User entered 'US'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '5'	System	10 Nov 2020 16:46:35
User entered '4'	System	27 Oct 2020 13:25:47
User entered '3'	System	26 Oct 2020 15:27:10
User entered '2'	System	05 Oct 2020 13:59:22
User entered '1'	System	25 Sep 2020 12:16:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:00
User entered '10/Nov/2020 16:46'	System	10 Nov 2020 16:46:35

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:01
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 16:46:35

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:26
User entered '21/Oct/2020 19:35'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:43
User entered '26/Oct/2020 14:17'	System	26 Oct 2020 14:17:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:37:16
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 14:17:37

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:02
User entered '30/Oct/2020 13:37'	System	30 Oct 2020 13:37:29

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 15:37:16
User entered 'I'		30 Oct 2020 13:37:29

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:20
User entered '06/Nov/2020 10:37'	System	06 Nov 2020 15:37:27

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:22:53
DataPoint Verified.		18 Nov 2020 16:55:22
User entered 'I'		06 Nov 2020 15:37:27

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:37
User entered '09/Nov/2020 10:13'	System	09 Nov 2020 15:13:58

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:22:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:39
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 15:13:58

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'USA-US090-2020-MRNA-1273-P301000006'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Yes (Y)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'No (N)'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:21
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Richard'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:23
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Glover'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '700 Medical Center Dr.'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'Newton'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:31
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered 'KS'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 19:35:16
User entered '67114'	System	21 Oct 2020 19:34:38

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:29:35
User entered 'US'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '6'	System	23 Nov 2020 20:23:10
User entered '5'	System	09 Nov 2020 15:13:58
User entered '4'	System	06 Nov 2020 15:37:27
User entered '3'	System	30 Oct 2020 13:37:29
User entered '2'	System	26 Oct 2020 14:17:37
User entered '1'	System	21 Oct 2020 19:35:23

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '23/Nov/2020 15:23'	(b) (4) System	23 Nov 2020 20:23:10

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 20:23:10

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'USA-US090-2020-MRNA-1273-P301000009'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Richard'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Glover'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '700 Medical Center Dr.'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Newton'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'KS'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '67114'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:53:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
User entered 'US'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	07 Jan 2021 14:54:00
User entered '1'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'USA-US090-2020-MRNA-1273-P301000009'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Richard'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Glover'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '700 Medical Center Dr.'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Newton'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'KS'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '67114'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:53:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
User entered 'US'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	07 Jan 2021 14:54:00
User entered '1'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
User entered '10/Nov/2020 15:14'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:53:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered	System	10 Nov 2020 20:14:19
'USA-US090-2020-MRNA-1273-P301000009'		

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'No (N)'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Richard'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Glover'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '700 Medical Center Dr.'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Newton'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'KS'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '67114'	System	10 Nov 2020 20:14:19

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:53:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:08
User entered 'US'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User entered '2'	System	07 Jan 2021 14:54:00
User entered '1'	System	10 Nov 2020 20:15:01

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
User entered '07/Jan/2021 14:53'	(b) (4) System	07 Jan 2021 14:54:00

US3062265

Folder: SAE USA-US090-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 21:46:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 14:54:00