

US3082269 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:06:46

All time stamps listed in this document are displayed in GMT

US3082269

**Form: Participant Creation**

**Data signed:** (b) (4) 05 Mar 2021 17:06:04

**Generated On: 09 Jun 2021 15:06:46**

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[Participant ID](#)

US3082269

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

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US3082269

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 21 SEP 2020

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

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Folder OID SCRN

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US3082269

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
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	False
Black	False
Asian	False
American Indian or Alaska Native	True
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) 05 Mar 2021 17:06:06

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Date of Informed Consent (*dd MMM yyyy*) 21 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 17:06:06

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 17:06:06

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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) 05 Mar 2021 17:06:06

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Condition	URINARY RETENTION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3082269

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	21 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: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:06:06

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Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 21 SEP 2020

Time of assessment (*00:00-23:59*) 11:30 (24 HR)

Vital Signs Date and Time (derived) 21 SEP 2020 11:30

Height (*xxx.x*) 68.5 in

Weight (*xxx.x*) 168.8 lb

BMI (*xxx.x*) 25.34552 kg/m<sup>2</sup>

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

21 SEP 2020

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

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US3082269

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:06:06

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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) 05 Mar 2021 17:06:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:06:07

Generated On: 09 Jun 2021 15:06:46

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 21 SEP 2020

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

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Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 191142

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) 05 Mar 2021 17:06:07

Generated On: 09 Jun 2021 15:06:46

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Height	ND - Not Done
Weight	ND - Not Done

---

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 17:06:07

Generated On: 09 Jun 2021 15:06:46

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 ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:30 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:30
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 17:06:07

Generated On: 09 Jun 2021 15:06:46

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 ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:14 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:14
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

21 SEP 2020

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

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US3082269

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 12:39 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 21 SEP 2020

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Collection time (*00:00-23:59*) 12:16 (24 HR)

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Collection date and time (derived) 21 SEP 2020 12:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Collection date ( <i>dd MMM yyyy</i> )			21 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:22	21 SEP 2020 12:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp 21 SEP 2020 13:12

PC Open Date & Time 21 SEP 2020 12:59

PC Close Date & Time 21 SEP 2020 15:29

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**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 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 21 SEP 2020 19:01  
PC Open Date & Time 21 SEP 2020 16:24  
PC Close Date & Time 22 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 19:30
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 19:52
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 18:24
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 19:35
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 SEP 2020 17:52
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.4 °F

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

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

PC Time Stamp 27 SEP 2020 17:23

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**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

21 SEP 2020 13:13

PC Open Date & Time

21 SEP 2020 12:59

PC Close Date & Time

21 SEP 2020 15:29

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**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

21 SEP 2020 16:24

PC Close Date & Time

22 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 2

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	22 SEP 2020 19:31
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 3

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 19:53
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 4

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	24 SEP 2020 18:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 5

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	25 SEP 2020 19:37
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 6

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

26 SEP 2020 17:52

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

DAY 7

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

27 SEP 2020 17:24

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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

No

Yes

PC Time stamp	21 SEP 2020 13:14
PC Open Date & Time	21 SEP 2020 12:59
PC Close Date & Time	21 SEP 2020 15:29

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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

No

Yes

PC Time stamp

PC Open Date & Time

21 SEP 2020 16:24

PC Close Date & Time

22 SEP 2020 11:59

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 19:33
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

---

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**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



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 19:55
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

---

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 18:26
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

---

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 19:39
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

---

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**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

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 17:54
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

---

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**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



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

---

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 17:25
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

---

US3082269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (dd MMM yyyy)

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

Comments

*If Contact Not Made, please provide Comments*

CONTACT WAS NOT  
ATTEMPTED DUE TO PATIENT  
BEING DISCONTINUED FROM  
THE STUDY BECAUSE OF SAE.

US3082269

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:06:06

Generated On: 09 Jun 2021 15:06:46

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

US3082269

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:06:46

---

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
---	--	---------------------------

---

---

US3082269

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:46

---

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"/>

---

US3082269

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:06:46

---

Generate Next COVID-19 Assessment

Yes

No

---

**US3082269**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:06:46**

---

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 \_\_\_\_\_

US3082269

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

Form: Unblinding

Generated On: 09 Jun 2021 15:06:46

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 \_\_\_\_\_



US3082269

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:46

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3082269

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:46

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00 - 23:59*) \_\_\_\_\_

Collection Date and Time (derived) \_\_\_\_\_

US3082269

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

AEID USA-US114-2020-MRNA-1273-P30  
1000003

Adverse event INTRA-ABDOMINAL  
PERFORATION

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) 02 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) 03 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 True

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 02 OCT 2020

Hospital Discharge Date (dd MMM yyyy) 3 OCT 2020

Admitted to ICU? Yes   
No   
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

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

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

---

SUBJECT ADMITTED FOR  
ESOPHAGEAL HERNIA, WHICH  
PROGRESSED VERY QUICKLY.  
THIS WAS REPORTED TO SITE  
BY THE GRANDDAUGHTER.  
SHE REPORTED THAT IT "WENT  
TO HIS LUNGS" SUBJECT  
EXPIRED ON 03OCT2020  
RECORDS HAVE BEEN  
REQUESTED. AFTER  
RECEIVING RECORDS IT WAS  
DETERMINED SUBJECT HAD A  
PNEUMOPERITONEUM AND  
INTRA-ABDOMINAL  
PERFORATION THAT LED TO  
CARDIAC ARREST

---

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)	1

---

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

AEID USA-US114-2020-MRNA-1273-P30  
1000006

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) 02 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) 3 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

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

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 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)	



US3082269

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

AEID

Adverse event

NEW ONSET ATRIAL  
FIBRILLATION

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)

02 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)

3 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 (3)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

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 checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PATIENT DIED FROM COMPLICATIONS OF FATAL SAE
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)	

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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

Yes

No

---

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

---

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication TAMSULOSIN

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 (1)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2019

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication COLCHICINE

Prophylaxis Yes   
No

Indication GOUT (BOTH FEET)

Dose per administration 0.6

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) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2018

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication TADALAFIL

Prophylaxis Yes   
No

Indication ERECTILE DYSFUNCTION

Dose per administration 2.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2019

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 17:06:05

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Name of Medication ALBUMIN (HUMAN) 5%

Prophylaxis Yes   
No

Indication SHOCK R/T SAE #1

Dose per administration 25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 17:06:05

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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 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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication ABDOMINAL PAIN

Dose per administration 162

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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*) 02 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication ATROPINE

Prophylaxis Yes   
No

Indication ATRIAL FIBRILLATION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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*) 02 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication DILTIAZEM (CARDIZEM)

Prophylaxis Yes   
No

Indication ATRIAL FIBRILLATION

Dose per administration 30

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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*) 02 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication DILTIAZEM (CARDIZEM)

Prophylaxis Yes   
No

Indication ATRIAL FIBRILLATION

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
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US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication ETOMIDATE (AMIDATE)

Prophylaxis Yes   
No

Indication ANAESTHETIC FOR SAE

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication FENTANYL

Prophylaxis Yes   
No

Indication ABDOMINAL 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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 03 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication IOPAMIDOL 76%

Prophylaxis Yes   
No

Indication CT IMAGING CONTRAST / USED  
TO DIAGNOSE  
PNEUMOPERITONEUM

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 (11)

Data signed: (b) (4) 05 Mar 2021 17:06:05

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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) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication LACTATED RINGERS BOLUS

Prophylaxis Yes   
No

Indication REPLACING  
FLUIDS/ELECTROLYTES

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

	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) 03 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 03 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication NOREPINEPHRINE

Prophylaxis Yes   
No

Indication BLOOD PRESSURE

Dose per administration 16/250

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MG/ML

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 THREE TIMES

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication PHENYLEPHRINE 0.9%

Prophylaxis Yes   
No

Indication BLOOD PRESSURE

Dose per administration 80/250

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MG/ML

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 THREE TIMES

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication PIPERACILLIN-TAZOBACTAM-D  
EXTRS (ZOSYN)

Prophylaxis Yes   
No

Indication INFECTION PREVENTATIVE

Dose per administration 3.375

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



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

	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) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication ROCURONIUM

Prophylaxis Yes   
No

Indication PARALYTIC

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 (16)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication SODIUM BICARBONATE 8.4%

Prophylaxis Yes   
No

Indication ELECTROLYTE REPLACEMENT

Dose per administration 100/1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MEQ/ML

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication SODIUM BICARBONATE 8.4%

Prophylaxis Yes   
No

Indication ELECTROLYTE REPLACEMENT

Dose per administration 150/1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MEQ/ML

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) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication SODIUM BICARBONATE 8.4%

Prophylaxis Yes   
No

Indication ELECTROLYTE REPLACEMENT

Dose per administration 50/1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MEQ/ML

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 17:06:05

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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 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*) 03 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication SODIUM BICARBONATE 5%

Prophylaxis Yes   
No

Indication ELECTROLYTE REPLACEMENT

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 17:06:05

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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 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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 03 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes   
No

Indication REPLACING FLUIDS

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

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*) 02 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication VANCOMYCIN

Prophylaxis Yes   
No

Indication INFECTION PREVENTION

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

117 of 1355

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Name of Medication VASOPRESSIN

Prophylaxis Yes   
No

Indication BLOOD PRESSURE

Dose per administration 100/100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify IU/ML

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

119 of 1355



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 OCT 2020	CT ANGIOGRAM OF THE CHEST	Adverse Event	
2 OCT 2020	CHEST X-RAY	Adverse Event	
2 OCT 2020	CENTRAL LINE PLACEMENT	Adverse Event	
2 OCT 2020	INTUBATION	Adverse Event	

US3082269

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

---

Date of dosing discontinuation (dd MMM yyyy) 03 OCT 2020

---

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Due to SARS-COV-2

Other

---

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

---

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:06:05

Generated On: 09 Jun 2021 15:06:46

Date of study discontinuation/completion (*dd MMM yyyy*) 03 OCT 2020

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify \_\_\_\_\_

Date of death (*dd MMM yyyy*) 03 OCT 2020

Was autopsy performed?

Yes

No

Unknown

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P30 1000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/OCT/2020 12:57
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/OCT/2020 14:29
<b>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.</b>	True



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/OCT/2020 12:21
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:01
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 11:06
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:28
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	21/NOV/2020 01:39
<b>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.</b>	False

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/MAR/2021 11:27
<b>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.</b>	<input checked="" type="checkbox"/> True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 22:03:02

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/APR/2021 12:05
<b>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.</b>	True

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 12:36:39

Generated On: 09 Jun 2021 15:06:46

SAEID	USA-US114-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 12:36:39

Generated On: 09 Jun 2021 15:06:46

SAEID USA-US114-2020-MRNA-1273-P30  
1000006

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name BARTON

Investigator's Last Name WILLIAMS

Site Address: Street 3806 PEACHTREE AVE.

Site Address: City WILMINGTON

Site Address: State NC

Site Address: Postal Code 28403

Investigator Country US

E2B Transmit Flag (Derived/Hidden)

Date of submission (Pre-filled from custom function)

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit

US3082269 (Prod: Trial Management Associates LLC - ERN - PPDS)

US3082269

Form: Participant Creation

Generated On: 09 Jun 2021 15:06:46

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:46
User entered 'US3082269'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 15:21:09

US3082269

Form: Participant Creation

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:53
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:44:44

US3082269

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:53
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 15:21:10

US3082269

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:53
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:44:44

US3082269

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'SCRN'	System	21 Sep 2020 16:44:44



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Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 15:21:11

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '75'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'YEARS'	System	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '75'	System	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered 'Male (M)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17



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Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '1'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:53:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:17

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30



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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'Sep 2020'	System	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '2020'	System	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 16:45:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 16:45:37
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 16:45:30
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:30

US3082269

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 15:21:10



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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	21 Sep 2020 16:45:44

US3082269

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:24
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:44

US3082269

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:06:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:30
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:45:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
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) (b) (4)	21 Sep 2020 17:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:34:42
Data point term sent to Coder	System	21 Sep 2020 17:33:55
User entered 'Urinary retention'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'UN UNK 2019'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51



US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'Jan 2019'	System	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '2019'	System	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:33:51

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:35:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:35:41
Data point term sent to Coder	System	21 Sep 2020 17:34:57
User entered 'Gout (both feet)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'UN UNK 2018'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13



US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'Jan 2018'	System	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '2018'	System	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:34:13

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:35:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:35:41
Data point term sent to Coder	System	21 Sep 2020 17:35:00
User entered 'Erectile dysfunction'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42



US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'UN UNK 2019'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'Jan 2019'	System	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '2019'	System	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:34:42



US3082269

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:34:42

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:53:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:53:34
Data point term sent to Coder	System	22 Oct 2020 15:52:26
User entered 'Hiatal Hernia'	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '21 Feb 2020'	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered empty.	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:44
User entered '0'	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered 'Feb 2020'	System	22 Oct 2020 15:52:03



US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '2020'	System	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	22 Oct 2020 15:52:03

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered '11:30'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 11:30'	System	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered '68.5' in	Alice Cipollini (b) (4)	21 Sep 2020 16:46:40
DataPoint set to visible.	(b) (4) System	21 Sep 2020 16:45:44



US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered '168.8' lb	Alice Cipollini (b) (4)	21 Sep 2020 16:46:40
DataPoint set to visible.	(b) (4) System	21 Sep 2020 16:45:44

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '25.34552'	System	21 Sep 2020 16:46:40
DataPoint set to visible.	System	21 Sep 2020 16:45:44

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'kg/m2'	System	21 Sep 2020 16:46:40
DataPoint set to visible.	System	21 Sep 2020 16:45:44

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:23:38
User closed query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:33:23
Query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	15 Dec 2020 14:18:13
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	15 Dec 2020 14:18:08
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	15 Dec 2020 14:18:08
User opened query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 13:45:26
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered 'Other (Other)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:23:38
User closed query 'Per CDM: When temperature is recorded as "ND", "If Other, specify" fields should remain empty. Please update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:25:17
Query 'Per CDM: When temperature is recorded as "ND", "If Other, specify" fields should remain empty. Please update accordingly. Thank you. ' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	16 Dec 2020 19:33:40
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	16 Dec 2020 19:32:31
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	16 Dec 2020 19:32:31
User opened query 'Per CDM: When temperature is recorded as "ND", "If Other, specify" fields should remain empty. Please update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 19:26:11
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'bpm'	System	21 Sep 2020 16:46:40



US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'breaths/min'	System	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:54:56
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 16:46:40

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41

US3082269

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41



US3082269

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:13
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:12

US3082269

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:13
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:12

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

**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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

**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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered '0'	(b) (4) Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered '1'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered '0'	(b) (4) Alice Cipollini (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:33
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:42

US3082269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:56
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:57



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:56
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:57

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:55:56
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:47:57

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'VISIT1'	System	21 Sep 2020 16:47:57

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 16:20:44

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered '191142'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 16:20:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Sep 2020 16:20:44

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:48:59

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:48:59



US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:48:59

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:48:59

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:48:59

US3082269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:01
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Sep 2020 16:48:59
DataPoint set to visible.	(b) (4) System	21 Sep 2020 16:45:37

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User accepted default value 'Pre-Dose (PREDOSE)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '11:30'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 11:30'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '98.5' F	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered 'Oral (Oral)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '62'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'bpm'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '17'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'breaths/min'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '127'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '79'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 17:36:17



US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered missing code ND - Not Done.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User accepted default value 'Post-Dose (POSTDOSE)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '13:14'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 13:14'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '98.0' F	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17



US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered 'Oral (Oral)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '60'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'bpm'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '16'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'breaths/min'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '119'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 17:36:17



US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:07
User entered '80'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'mmHg'	System	21 Sep 2020 17:36:17

US3082269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:13
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:49:54

US3082269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:13
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:49:54

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:50:26



US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered '12:39'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 12:39'	System	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered 'Left Arm (LEFT ARM)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 17:56:17
User entered 'ONCE'	System	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:50:26

US3082269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:44
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:52

US3082269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:44
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:52



US3082269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:44
User entered '12:16'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:50:52

US3082269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 12:16'	System	21 Sep 2020 16:50:52

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:06:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:50
User entered '21 Sep 2020'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:50
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:50
User entered '12:22'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '21 Sep 2020 12:22'	System	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17



US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:50
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:56:50
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered empty.	System	21 Sep 2020 16:51:17

US3082269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:00
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:26

US3082269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:41
User entered '1'	System	21 Sep 2020 17:36:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:11:27', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9c1d6899-84d0-49eb-a1cb-ae9c0c2f6d18' User entered 'Yes (Y)'	System	21 Sep 2020 17:14:49
	System	21 Sep 2020 17:14:49

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:11:50', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9c1d6899-84d0-49eb-a1cb-ae9c0c2f6d18' User entered '98.0'	System	21 Sep 2020 17:14:49
	System	21 Sep 2020 17:14:49



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:11:59', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9c1d6899-84d0-49eb-a1cb-ae9c0c2f6d18' User entered 'No (N)'	System	21 Sep 2020 17:14:49
	System	21 Sep 2020 17:14:49

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:12:17', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9c1d6899-84d0-49eb-a1cb-ae9c0c2f6d18' User entered '21 Sep 2020 13:12'	System	21 Sep 2020 17:14:49
	System	21 Sep 2020 17:14:49

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 12:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 15:29'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T19:00:35', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'c256d275-18ce-4c1a-bf05-457953f3bcb0' User entered 'Yes (Y)'	System	21 Sep 2020 23:01:59
	System	21 Sep 2020 23:01:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T19:00:50', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'c256d275-18ce-4c1a-bf05-457953f3bcb0' User entered '96.6'	System	21 Sep 2020 23:01:59
	System	21 Sep 2020 23:01:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T19:00:59', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'c256d275-18ce-4c1a-bf05-457953f3bcb0'	System	21 Sep 2020 23:01:59
User entered 'No (N)'	System	21 Sep 2020 23:01:59



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T19:01:57', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'c256d275-18ce-4c1a-bf05-457953f3bcb0' User entered '21 Sep 2020 19:01'	System	21 Sep 2020 23:01:59
	System	21 Sep 2020 23:01:59

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 16:24'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 2'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:28:21', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '600cad88-d8bf-4c3b-a588-606921622b59' User entered 'Yes (Y)'	System	22 Sep 2020 23:30:47
	System	22 Sep 2020 23:30:47

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:30:05', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '600cad88-d8bf-4c3b-a588-606921622b59' User entered '97.6'	System	22 Sep 2020 23:30:47
	System	22 Sep 2020 23:30:47

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:28:47', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '600cad88-d8bf-4c3b-a588-606921622b59' User entered 'No (N)'	System	22 Sep 2020 23:30:47
	System	22 Sep 2020 23:30:47

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:30:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '600cad88-d8bf-4c3b-a588-606921622b59' User entered '22 Sep 2020 19:30'	System	22 Sep 2020 23:30:47
	System	22 Sep 2020 23:30:47



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 3'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:51:46', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '6c06f19f-48c6-4b89-a49b-1a63556830fb' User entered 'Yes (Y)'	System	23 Sep 2020 23:52:40
	System	23 Sep 2020 23:52:40

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:52:03', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '6c06f19f-48c6-4b89-a49b-1a63556830fb' User entered '97.5'	System	23 Sep 2020 23:52:40
	System	23 Sep 2020 23:52:40

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:52:12', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '6c06f19f-48c6-4b89-a49b-1a63556830fb' User entered 'No (N)'	System	23 Sep 2020 23:52:40
	System	23 Sep 2020 23:52:40

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:52:38', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '6c06f19f-48c6-4b89-a49b-1a63556830fb' User entered '23 Sep 2020 19:52'	System	23 Sep 2020 23:52:40
	System	23 Sep 2020 23:52:40

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 4'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:23:58', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '40c159de-2b20-4bf4-8fff-adb12a141771' User entered 'Yes (Y)'	System	24 Sep 2020 22:24:50
	System	24 Sep 2020 22:24:50

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:24:09', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '40c159de-2b20-4bf4-8fff-adb12a141771'	System	24 Sep 2020 22:24:50
User entered '98.6'	System	24 Sep 2020 22:24:50

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:24:15', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '40c159de-2b20-4bf4-8fff-adb12a141771'	System	24 Sep 2020 22:24:50
User entered 'No (N)'	System	24 Sep 2020 22:24:50

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:24:45', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '40c159de-2b20-4bf4-8fff-adb12a141771'	System	24 Sep 2020 22:24:50
User entered '24 Sep 2020 18:24'	System	24 Sep 2020 22:24:50

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 5'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:35:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'fbf6376f-e9a6-49e6-b373-29d9348ed63b' User entered 'Yes (Y)'	System	25 Sep 2020 23:35:58
	System	25 Sep 2020 23:35:58

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:35:29', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'fbf6376f-e9a6-49e6-b373-29d9348ed63b' User entered '98.6'	System	25 Sep 2020 23:35:58
	System	25 Sep 2020 23:35:58

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:35:40', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'fbf6376f-e9a6-49e6-b373-29d9348ed63b'	System	25 Sep 2020 23:35:58
User entered 'No (N)'	System	25 Sep 2020 23:35:58

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:35:56', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'fbf6376f-e9a6-49e6-b373-29d9348ed63b' User entered '25 Sep 2020 19:35'	System	25 Sep 2020 23:35:58
	System	25 Sep 2020 23:35:58

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 6'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:51:23', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '1adb6fee-72ec-45ad-bad2-28a68440c94a' User entered 'Yes (Y)'	System	26 Sep 2020 21:52:08
	System	26 Sep 2020 21:52:08

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:51:35', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '1adb6fee-72ec-45ad-bad2-28a68440c94a' User entered '98.0'	System	26 Sep 2020 21:52:08
	System	26 Sep 2020 21:52:08

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:51:42', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '1adb6fee-72ec-45ad-bad2-28a68440c94a' User entered 'No (N)'	System	26 Sep 2020 21:52:08
	System	26 Sep 2020 21:52:08

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '1adb6fee-72ec-45ad-bad2-28a68440c94a' User entered '26 Sep 2020 17:52'	System	26 Sep 2020 21:52:08
	System	26 Sep 2020 21:52:08

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 7'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:22:37', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2d334bfa-12e1-43ef-b1a4-52abeeaa5293' User entered 'Yes (Y)'	System	27 Sep 2020 21:23:11
	System	27 Sep 2020 21:23:11



US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:22:50', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2d334bfa-12e1-43ef-b1a4-52abeeaa5293'	System	27 Sep 2020 21:23:11
User entered '97.4'	System	27 Sep 2020 21:23:11

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:22:55', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2d334bfa-12e1-43ef-b1a4-52abeeaa5293'	System	27 Sep 2020 21:23:11
User entered 'No (N)'	System	27 Sep 2020 21:23:11

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:23:10', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2d334bfa-12e1-43ef-b1a4-52abeeaa5293'	System	27 Sep 2020 21:23:11
User entered '27 Sep 2020 17:23'	System	27 Sep 2020 21:23:11

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:12:59', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'e916a987-83e6-4d30-8640-69ed8cdb0691'	System	21 Sep 2020 17:15:25
User entered 'None (1)'	System	21 Sep 2020 17:15:25

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:12:38', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'e916a987-83e6-4d30-8640-69ed8cdb0691' User entered 'No (N)'	System	21 Sep 2020 17:15:25
	System	21 Sep 2020 17:15:25



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:12:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'e916a987-83e6-4d30-8640-69ed8cdb0691'	System	21 Sep 2020 17:15:25
User entered 'No (N)'	System	21 Sep 2020 17:15:25

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:12:49', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'e916a987-83e6-4d30-8640-69ed8cdb0691'	System	21 Sep 2020 17:15:25
User entered 'None (1)'	System	21 Sep 2020 17:15:25

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:09', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'e916a987-83e6-4d30-8640-69ed8cdb0691' User entered '21 Sep 2020 13:13'	System	21 Sep 2020 17:15:25
	System	21 Sep 2020 17:15:25

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 12:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 15:29'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 16:24'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 2'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:31:12', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '566171fc-9dbe-4895-8a18-a1119fddf933'	System	22 Sep 2020 23:31:58
User entered 'None (1)'	System	22 Sep 2020 23:31:58

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:31:18', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '566171fc-9dbe-4895-8a18-a1119fddf933'	System	22 Sep 2020 23:31:58
User entered 'No (N)'	System	22 Sep 2020 23:31:58

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:31:23', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '566171fc-9dbe-4895-8a18-a1119fddf933'	System	22 Sep 2020 23:31:58
User entered 'No (N)'	System	22 Sep 2020 23:31:58

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:31:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '566171fc-9dbe-4895-8a18-a1119fddf933'	System	22 Sep 2020 23:31:58
User entered 'None (1)'	System	22 Sep 2020 23:31:58

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:31:55', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '566171fc-9dbe-4895-8a18-a1119fddf933' User entered '22 Sep 2020 19:31'	System	22 Sep 2020 23:31:58
	System	22 Sep 2020 23:31:58

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 3'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:52:53', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4d4c6761-7a7e-47ff-9147-965aacia0a15'	System	23 Sep 2020 23:53:35
User entered 'None (1)'	System	23 Sep 2020 23:53:35

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:52:58', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4d4c6761-7a7e-47ff-9147-965aacia0a15'	System	23 Sep 2020 23:53:35
User entered 'No (N)'	System	23 Sep 2020 23:53:35

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:53:03', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4d4c6761-7a7e-47ff-9147-965aaca0a15'	System	23 Sep 2020 23:53:35
User entered 'No (N)'	System	23 Sep 2020 23:53:35

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:53:14', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4d4c6761-7a7e-47ff-9147-965aacia0a15'	System	23 Sep 2020 23:53:35
User entered 'None (1)'	System	23 Sep 2020 23:53:35

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:53:32', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4d4c6761-7a7e-47ff-9147-965aacia0a15'	System	23 Sep 2020 23:53:35
User entered '23 Sep 2020 19:53'	System	23 Sep 2020 23:53:35

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 4'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:00', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '76660323-ab6b-4a60-a3df-79f10df25e0f' User entered 'None (1)'	System	24 Sep 2020 22:25:37
	System	24 Sep 2020 22:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '76660323-ab6b-4a60-a3df-79f10df25e0f' User entered 'No (N)'	System	24 Sep 2020 22:25:37
	System	24 Sep 2020 22:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:09', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '76660323-ab6b-4a60-a3df-79f10df25e0f' User entered 'No (N)'	System	24 Sep 2020 22:25:37
	System	24 Sep 2020 22:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:16', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '76660323-ab6b-4a60-a3df-79f10df25e0f' User entered 'None (1)'	System	24 Sep 2020 22:25:37
	System	24 Sep 2020 22:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:30', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '76660323-ab6b-4a60-a3df-79f10df25e0f' User entered '24 Sep 2020 18:25'	System	24 Sep 2020 22:25:37
	System	24 Sep 2020 22:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 5'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:36:13', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '797b57a9-298f-4031-8416-692da8a727af' User entered 'None (1)'	System	25 Sep 2020 23:37:41
	System	25 Sep 2020 23:37:41

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:36:21', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '797b57a9-298f-4031-8416-692da8a727af' User entered 'No (N)'	System	25 Sep 2020 23:37:41
	System	25 Sep 2020 23:37:41

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:37:14', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '797b57a9-298f-4031-8416-692da8a727af' User entered 'No (N)'	System	25 Sep 2020 23:37:41
	System	25 Sep 2020 23:37:41

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:36:41', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '797b57a9-298f-4031-8416-692da8a727af'	System	25 Sep 2020 23:37:41
User entered 'None (1)'	System	25 Sep 2020 23:37:41

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:37:39', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '797b57a9-298f-4031-8416-692da8a727af' User entered '25 Sep 2020 19:37'	System	25 Sep 2020 23:37:41
	System	25 Sep 2020 23:37:41

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 6'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:12', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '125a9984-93a8-4ad4-b486-fce41435bac4'	System	26 Sep 2020 21:52:55
User entered 'None (1)'	System	26 Sep 2020 21:52:55

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:18', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '125a9984-93a8-4ad4-b486-fce41435bac4' User entered 'No (N)'	System	26 Sep 2020 21:52:55
	System	26 Sep 2020 21:52:55

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:26', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '125a9984-93a8-4ad4-b486-fce41435bac4' User entered 'No (N)'	System	26 Sep 2020 21:52:55
	System	26 Sep 2020 21:52:55

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:34', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '125a9984-93a8-4ad4-b486-fce41435bac4'	System	26 Sep 2020 21:52:55
User entered 'None (1)'	System	26 Sep 2020 21:52:55

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:52:49', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '125a9984-93a8-4ad4-b486-fce41435bac4' User entered '26 Sep 2020 17:52'	System	26 Sep 2020 21:52:55
	System	26 Sep 2020 21:52:55

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 7'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:23:18', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '36e31546-b323-462f-81d7-300227dae564'	System	27 Sep 2020 21:24:12
User entered 'None (1)'	System	27 Sep 2020 21:24:12

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:23:25', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '36e31546-b323-462f-81d7-300227dae564'	System	27 Sep 2020 21:24:12
User entered 'No (N)'	System	27 Sep 2020 21:24:12

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:23:31', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '36e31546-b323-462f-81d7-300227dae564' User entered 'No (N)'	System	27 Sep 2020 21:24:12
	System	27 Sep 2020 21:24:12

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:23:45', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '36e31546-b323-462f-81d7-300227dae564'	System	27 Sep 2020 21:24:12
User entered 'None (1)'	System	27 Sep 2020 21:24:12

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:06', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '36e31546-b323-462f-81d7-300227dae564' User entered '27 Sep 2020 17:24'	System	27 Sep 2020 21:24:12
	System	27 Sep 2020 21:24:12

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:21', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:26', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:32', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:38', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:13:49', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'None (0)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:14:03', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered 'No (N)'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-21T13:14:17', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'd65633e1-8ce3-4501-9fd4-22f6c2ec2dba' User entered '21 Sep 2020 13:14'	System	21 Sep 2020 17:16:01
	System	21 Sep 2020 17:16:01



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 12:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 15:29'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '21 Sep 2020 16:24'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 2'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:14', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0'	System	22 Sep 2020 23:33:38
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:19', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0'	System	22 Sep 2020 23:33:38
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:33:38



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:26', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0' User entered 'None (0)'	System	22 Sep 2020 23:33:38
	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:34', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0'	System	22 Sep 2020 23:33:38
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:41', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0' User entered 'None (0)'	System	22 Sep 2020 23:33:38
	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:32:46', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0' User entered 'None (0)'	System	22 Sep 2020 23:33:38
	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:33:00', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0' User entered 'No (N)'	System	22 Sep 2020 23:33:38
	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-22T19:33:33', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ef15d47-1345-49f3-8bcc-3b434e2088f0' User entered '22 Sep 2020 19:33'	System	22 Sep 2020 23:33:38
	System	22 Sep 2020 23:33:38

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 3'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:53:47', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:55:12', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:53:58', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:54:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:55:05', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:54:14', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'None (0)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:54:25', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered 'No (N)'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-23T19:55:34', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '2f3a3861-5071-4116-8a5f-8d7e746f93be' User entered '23 Sep 2020 19:55'	System	23 Sep 2020 23:55:37
	System	23 Sep 2020 23:55:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 4'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:52', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:25:58', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:07', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:12', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:16', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:19', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'None (0)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:34', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered 'No (N)'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-24T18:26:59', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '7a4ab542-b99d-44fd-ac4a-4573f1fa88ce' User entered '24 Sep 2020 18:26'	System	24 Sep 2020 22:27:01
	System	24 Sep 2020 22:27:01

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 5'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:37:57', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'None (0)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:38:02', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'None (0)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:39:07', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'None (0)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:38:18', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa'	System	25 Sep 2020 23:39:31
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:38:24', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'None (0)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:38:28', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'None (0)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:38:41', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered 'No (N)'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-25T19:39:27', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '4ba79c3e-400e-4258-9c92-109919e939aa' User entered '25 Sep 2020 19:39'	System	25 Sep 2020 23:39:31
	System	25 Sep 2020 23:39:31

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:50:26



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 6'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:14', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:19', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:24', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:28', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:36', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'None (0)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:53:46', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered 'No (N)'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-26T17:54:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: 'f7302fe7-d8cf-4ef9-91cf-a3839c85281e' User entered '26 Sep 2020 17:54'	System	26 Sep 2020 21:54:45
	System	26 Sep 2020 21:54:45

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Data entry locked.	System	21 Sep 2020 16:50:26
User entered 'Day 7'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:20', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered 'None (0)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:24', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered 'None (0)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:28', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11fee'	System	27 Sep 2020 21:25:37
User entered 'None (0)'	System	27 Sep 2020 21:25:37



US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:35', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11fceb' User entered 'None (0)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:43', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered 'None (0)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:24:52', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered 'None (0)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:25:04', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered 'No (N)'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6463D76F-7C49-4BB9-8A0D-F189C8677B29)', Time: '2020-09-27T17:25:30', User OID: 'PatientReportedOutcome (US3082269)', ODM File OID: '9a760e0d-8a9e-4cf5-b107-466bf11ffeb' User entered '27 Sep 2020 17:25'	System	27 Sep 2020 21:25:37
	System	27 Sep 2020 21:25:37

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:50:26

US3082269

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:06:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:50:26

US3082269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:11
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	15 Oct 2020 19:05:45



US3082269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:11
User entered empty.	Megan Marles (b) (4) (b) (4)	15 Oct 2020 19:05:45

US3082269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:11
User entered empty.	Megan Marles (b) (4) (b) (4)	15 Oct 2020 19:05:45

US3082269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:32:49
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	01 Feb 2021 18:27:59
User entered 'Contact was not attempted due to patient being discontinued from the study because of SAE.' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	01 Feb 2021 18:27:59
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 17:57:11
User entered empty.	Megan Marles (b) (4) (b) (4)	15 Oct 2020 19:05:45

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Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:57:18
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	15 Oct 2020 19:05:52

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Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	15 Oct 2020 19:05:52

US3082269

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:06:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:19:38
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:41:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:15
User entered 'USA-US114-2020-mRNA-1273-P301000003'	System	06 Oct 2020 12:57:08
User entered 'New'	(b) (4), (b) (6)	06 Oct 2020 12:57:08

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric perforation, LLT: Gastric perforation - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:52
Data point term sent to Coder	System	11 Mar 2021 14:54:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
Data point term sent to Coder	System	11 Mar 2021 14:52:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric perforation, LLT: Gastric perforation - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:13:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:13:03
Data point term sent to Coder	System	19 Nov 2020 17:57:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
Data point term sent to Coder	System	19 Nov 2020 17:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric perforation, LLT: Gastric perforation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 12:36:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 12:36:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Abdominal injury, LLT: Abdominal injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:40:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:40:33
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 13:06:45
User closed query 'PV Query: The event term contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:20:14
Data point term sent to Coder	System	22 Oct 2020 15:21:11
Query 'PV Query: The event term contains multiple event terms. Please consider separating them into separate events.' answered with 'Updated per PI' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:20:30
Coding entries removed.	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:20:12
User entered 'INTRA-ABDOMINAL PERFORATION' reason for change: Per Query Resolution	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:20:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 13:22:07
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User opened query 'PV Query: The event term contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:14:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Peritoneal and retroperitoneal conditions, HLT: Peritoneal and retroperitoneal disorders, PT: Pneumoperitoneum, LLT: Pneumoperitoneum - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 11:55:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 11:55:08
Data point term sent to Coder	System	05 Oct 2020 17:24:50
Coding entries removed.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User entered 'Pneumoperitoneum, presumed intra-abdominal perforation' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Esophageal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 13:52:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 13:52:25
Data point term sent to Coder	System	05 Oct 2020 13:51:21
User entered 'Esophageal Hernia'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '02 Oct 2020'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Oct 2020 17:25:25
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:25:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Oct 2020 17:24:25
User entered '11:42' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	05 Oct 2020 17:25:25
User entered '02 Oct 2020 11:42'	System	05 Oct 2020 17:24:25
User entered empty.	System	05 Oct 2020 13:51:15



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '03 Oct 2020'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Oct 2020 17:25:25
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:25:25
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Oct 2020 17:24:25
User entered '03:20' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	05 Oct 2020 17:25:25
User entered '03 Oct 2020 03:20'	System	05 Oct 2020 17:24:25
User entered empty.	System	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	05 Oct 2020 14:27:16
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 14:27:16
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	05 Oct 2020 13:51:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
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) (4), (b) (6)	24 Nov 2020 13:18:31
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 'DATA IS COMPLETED' (Site from System).	Erin Harrelson (b) (4) (b) (4)	19 Nov 2020 18:02:57
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	19 Nov 2020 17:56:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 05:43:53
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).	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:25:48
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Oct 2020 14:27:43
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	05 Oct 2020 14:27:43
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	05 Oct 2020 14:27:43
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 14:27:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Oct 2020 13:51:15
User entered '0'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '02 Oct 2020' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:03:02
Data hard locked.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:39
User closed query 'PER SAE RECON: Ongoing recorded as 'NO', however hospital discharge date is missing. Kindly review and update. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:55:21
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:36:41
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:06:38
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:06:38
Query 'PER SAE RECON: Ongoing recorded as 'NO', however hospital discharge date is missing. Kindly review and update. ' answered with 'The patient was not discharged. Patient died at the hospital from complications. ' (Site from DM). User opened query 'PER SAE RECON: Ongoing recorded as 'NO', however hospital discharge date is missing. Kindly review and update. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Barton Williams (b) (4)	21 Apr 2021 19:05:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:50:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Apr 2021 12:36:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
User signature succeeded.	Barton Williams (b) (4)	11 Mar 2021 14:52:49
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Oct 2020 17:24:25
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		05 Oct 2020 17:24:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Oct 2020 13:51:15
User entered 'Unknown (UNK)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	05 Oct 2020 17:24:25
User entered empty.	(b) (4) Flo Abbott (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	05 Oct 2020 17:24:25
User entered '0'	(b) (4) Flo Abbott (b) (4)	05 Oct 2020 13:51:15



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	05 Oct 2020 17:24:25
User entered '0'	(b) (4) Flo Abbott (b) (4)	05 Oct 2020 13:51:15
	(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)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 17:41:52
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:26:02
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 17:24:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 17:24:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:09:14
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Not Related (NOT RELATED)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:56
User closed query 'PV Query: Please update the action taken as "not applicable" since the subject died.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:27:49
Query 'PV Query: Please update the action taken as "not applicable" since the subject died.' answered with 'updated' (Site from Safety).	Erin Harrelson (b) (4) (b) (4)	13 Nov 2020 17:36:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	13 Nov 2020 17:08:35
User opened query 'PV Query: Please update the action taken as "not applicable" since the subject died.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:18:10
User closed query 'Per CDM: Please note that in the Dosing discontinuation form, Primary reason for dosing discontinuation = INTRA-ABDOMINAL PERFORATION. Kindly update the Action taken with investigational product field accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:30:59

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Please note that in the Dosing discontinuation form, Primary reason for dosing discontinuation = INTRA-ABDOMINAL PERFORATION. Kindly update the Action taken with investigational product field accordingly. Thank you. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	10 Nov 2020 18:14:00
	Alice Cipollini (b) (4) (b) (4)	10 Nov 2020 18:13:40
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	10 Nov 2020 18:13:40
User opened query 'Per CDM: Please note that in the Dosing discontinuation form, Primary reason for dosing discontinuation = INTRA-ABDOMINAL PERFORATION. Kindly update the Action taken with investigational product field accordingly. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 13:23:10
	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'None (NONE)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:31:06
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	05 Nov 2020 20:27:07
User entered '0' reason for change: Data Entry Error	Angie Northcott (b) (4)	05 Nov 2020 20:27:07
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	05 Nov 2020 20:25:55
DataPoint Un-verified.	Angie Northcott (b) (4)	05 Nov 2020 20:25:55
User entered '1' reason for change: Data Entry Error	(b) (4) Angie Northcott (b) (4)	05 Nov 2020 20:25:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Oct 2020 17:24:25



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Folder: Adverse Events

Form: Adverse Events (1)

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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).	System	05 Oct 2020 13:51:15
User entered '0'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:17:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:31:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'No action taken with investigational product ' (Site from DM).	Angie Northcott (b) (4) (b) (4)	05 Nov 2020 20:26:30
DataPoint Un-verified.	Angie Northcott (b) (4) (b) (4)	05 Nov 2020 20:25:55
User entered '0' reason for change: Data Entry Error	Angie Northcott (b) (4) (b) (4)	05 Nov 2020 20:25:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 09:07:18
	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	05 Oct 2020 17:24:25
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	05 Oct 2020 17:24:25
User entered '0'	(b) (4) Flo Abbott (b) (4)	05 Oct 2020 13:51:15

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Fatal (FATAL)'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PNEUMOPERITONEUM. Please review if this qualify to be recorded as a separate AE. Review and update eCRF. Otherwise, clarify. (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 10:51:59
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PNEUMOPERITONEUM. Please review if this qualify to be recorded as a separate AE. Review and update eCRF. Otherwise, clarify. answered with 'Added the AE' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	03 Dec 2020 19:00:06
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PNEUMOPERITONEUM. Please review if this qualify to be recorded as a separate AE. Review and update eCRF. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 00:16:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:15:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Subject was admitted with intra-abdominal perforation leading to cardiac arrest and cardiogenic shock. Please consider reporting additional SAE s Cardiac arrest and Cardiogenic shock.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:27:07
User closed query 'PV Query: Subject was admitted wit A fib with RVR. Please consider reporting additional SAE A-fib with RVR' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:27:04
User closed query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:27:02
User closed query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:26:58
Query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' answered with 'Hiatal hernia is what was diagnosed prior to the start of study and is listed in medical history' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	06 Nov 2020 19:22:42
Query 'PV Query: Subject was admitted with intra-abdominal perforation leading to cardiac arrest and cardiogenic shock. Please consider reporting additional SAE s Cardiac arrest and Cardiogenic shock.' answered with 'Per PI not a separate SAE' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	06 Nov 2020 19:18:29
Query 'PV Query: Subject was admitted wit A fib with RVR. Please consider reporting additional SAE A-fib with RVR' answered with 'Per PI not a separate SAE' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	06 Nov 2020 19:17:59
Query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' answered with 'Per PI not a separate SAE' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	06 Nov 2020 19:17:31
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:31:18
User opened query 'PV Query: Subject was admitted with intra-abdominal perforation leading to cardiac arrest and cardiogenic shock. Please consider reporting additional SAE s Cardiac arrest and Cardiogenic shock.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 23:26:50



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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Subject was admitted with A fib with RVR. Please consider reporting additional SAE A-fib with RVR' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 23:26:36
User opened query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 23:26:20
User opened query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 23:26:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 13:06:53
User closed query 'PV Query: Please clarify location of 'intra-abdominal' perforation. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:20:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:19:56
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:19:49
User closed query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:19:26
User closed query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:18:53
User closed query 'PV Query: Was SARS-CoV-2 testing done? If so, please provide date of testing and result.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:18:26
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:18:18

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:18:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Records faxed 22Oct2020' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:03:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Records faxed 22Oct2020' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:03:11
Query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records faxed 22Oct2020' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:02:54
Query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' answered with 'Hiatal Hernia added to medical history' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:54:38
Query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' answered with 'Per PI cardiac arrest is the result of Intra-abdominal perforation' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:40:11
Query 'PV Query: Please clarify location of "intra-abdominal" perforation. If unknown, please state so.' answered with 'stomach and colon' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:39:05
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Intra-abdominal perforation' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:37:50
DataPoint Un-verified.	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:37:28

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ADMITTED FOR ESOPHAGEAL HERNIA, WHICH PROGRESSED VERY QUICKLY. THIS WAS REPORTED TO SITE BY THE GRANDDAUGHTER. SHE REPORTED THAT IT "WENT TO HIS LUNGS" SUBJECT EXPIRED ON 03OCT2020 RECORDS HAVE BEEN REQUESTED. AFTER RECEIVING RECORDS IT WAS DETERMINED SUBJECT HAD A PNEUMOPERITONEUM AND INTRA-ABDOMINAL PERFORATION THAT LED TO CARDIAC ARREST' reason for change: New Information	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:37:28
Query 'PV Query: Was SARS-CoV-2 testing done? If so, please provide date of testing and result.' answered with 'No' (Site from Safety). DataPoint Verified.	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 15:21:36
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 13:21:24
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'UNKNOWN' (Site from Safety).	Erin Harrelson (b) (4) (b) (4)	15 Oct 2020 17:20:03
User opened query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:15:31
User opened query 'PV Query: Please clarify whether esophageal hernia is considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:15:24
User opened query 'PV Query: Please confirm whether cardiac arrest should be reported as separate SAE.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:15:14
User opened query 'PV Query: Please clarify location of "intra-abdominal" perforation. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:15:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

[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)	14 Oct 2020 15:14:41
User opened query 'PV Query: Was SARS-CoV-2 testing done? If so, please provide date of testing and result.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:14:35
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)	14 Oct 2020 15:14:28
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:14:20
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:14:13
User entered 'SUBJECT ADMITTED FOR ESOPHAGEAL HERNIA, WHICH PROGRESSED VERY QUICKLY. THIS WAS REPORTED TO SITE BY THE GRANDDAUGHTER. SHE REPORTED THAT IT "WENT TO HIS LUNGS" SUBJECT EXPIRED ON 03OCT2020 RECORDS HAVE BEEN REQUESTED. After receiving records it was determined subject had a pneumoperitoneum and intra-abdominal perforation that led to cardia arrest' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 17:24:25
User entered 'Subject admitted for Esophageal hernia, which progressed very quickly. This was reported to site by the granddaughter. She reported that it "went to his lungs" Subject expired on 03Oct2020 Records have been requested.'	Flo Abbott (b) (4) (b) (4)	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '1'	System	05 Oct 2020 13:51:15

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '1'	System	05 Oct 2020 13:51:15

US3082269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '1'	System	05 Oct 2020 17:24:25
User entered '0'	System	05 Oct 2020 13:51:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:55:24
User entered 'USA-US114-2020-mRNA-1273-P301000006' Un-reviewed for Safety.	System	21 Nov 2020 01:50:24
User entered 'New' reason for change: Data Entry Error Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:50:24
User entered 'USA-US114-2020-mRNA-1273-P301000003' DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Nov 2020 01:46:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Nov 2020 01:38:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:52
Data point term sent to Coder	System	11 Mar 2021 14:54:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
Data point term sent to Coder	System	11 Mar 2021 14:52:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 17:58:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 17:58:01
Data point term sent to Coder	System	19 Nov 2020 17:57:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
Data point term sent to Coder	System	19 Nov 2020 17:56:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:39:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:39:20
Data point term sent to Coder	System	07 Oct 2020 15:38:32
User entered 'Hyperglycemia'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	07 Oct 2020 15:37:59



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Jan 2021 14:22:56
DataPoint Un-verified.	(b) (4) Erin Harrelson (b) (4)	06 Jan 2021 13:03:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erin Harrelson (b) (4)	06 Jan 2021 13:03:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:52:26
DataPoint Un-verified.	Morgan Mathis (b) (4)	18 Nov 2020 14:53:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	18 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 13:07:03
DataPoint Un-verified.	Flo Abbott (b) (4)	22 Oct 2020 17:05:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Flo Abbott (b) (4)	22 Oct 2020 17:05:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4)	18 Jan 2021 14:22:56
User closed query 'Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please review and update as appropriate, else confirm in a query response that the AE stopped prior to subject's death.' (Site from DM).	Ayssa Valente (b) (4)	07 Jan 2021 21:50:30
Query 'Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please review and update as appropriate, else confirm in a query response that the AE stopped prior to subject's death.' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Erin Harrelson (b) (4)	06 Jan 2021 13:03:42
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	06 Jan 2021 13:03:36

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please review and update as appropriate, else confirm in a query response that the AE stopped prior to subject's death.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 08:31:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
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	19 Nov 2020 17:50:29
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	19 Nov 2020 17:50:29
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	19 Nov 2020 17:48:24
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	19 Nov 2020 13:11:50
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	19 Nov 2020 13:11:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:52:53
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	18 Nov 2020 14:54:11
DataPoint Un-verified.	Morgan Mathis (b) (4)	18 Nov 2020 14:53:59
User entered '3 Oct 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4)	18 Nov 2020 14:53:59

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Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please update as appropriate.  ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 07:04:09
	(b) (4), (b) (6)	26 Oct 2020 13:07:05
Query ' Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please update as appropriate. ' answered with 'updated' (Site from DM).	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:05:52
User entered empty; reason for change Data Entry Error DataPoint Un-verified.	Flo Abbott (b) (4) (b) (4) (b) (4), (b) (6)	22 Oct 2020 17:05:42
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:41:33
	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User opened query ' Per CDM: Per CCGs, AEs that were present at the time of death (and not the cause of death) should be reported as 'Not Recovered' and end date should be blank. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:57:07
Query 'Per CDM: Per CCGs, AEs that are ongoing at the time of death should not have an end date. Please update this field and the Outcome field as appropriate. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:56:42
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 09:51:28
User opened query 'Per CDM: Per CCGs, AEs that are ongoing at the time of death should not have an end date. Please update this field and the Outcome field as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:51:26

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Patient has died, see other AE. Hyperglycemia not the cause of death. End date is included to reflect this. Recovered has been recorded as unknown because it is not cause of death.' (Site from System).	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:51:16
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	12 Oct 2020 12:49:50
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	12 Oct 2020 12:47:13
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	12 Oct 2020 12:47:13
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	12 Oct 2020 12:46:59
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	07 Oct 2020 15:37:59



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:53
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 17:48:24
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 17:48:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	19 Nov 2020 17:48:16
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 17:47:32
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	19 Nov 2020 17:47:32
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 16:43:28
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 16:43:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 16:43:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 16:43:02
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 16:43:02
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 16:43:02
Comment added 'Although, hyperglycemia is noted as an AE it is not the primary cause of the subjects death'.	Ayssa Valente (b) (4)	19 Nov 2020 13:22:02
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 13:21:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 13:21:13
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 13:20:54
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 13:20:54
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 13:12:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 13:12:36
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 13:12:00
DataPoint Un-verified.	Ayssa Valente (b) (4)	19 Nov 2020 13:12:00
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 13:12:00
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Nov 2020 13:11:50
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	18 Nov 2020 14:54:11
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	18 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	12 Oct 2020 12:49:50
Comment added 'Outcome is fatal but it is not related to cause of death. Correct grade is 2.'	Brandy Lowman (b) (4)	12 Oct 2020 12:49:07
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	12 Oct 2020 12:47:13

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[Severity](#)

Audit	User	Time (GMT)
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	12 Oct 2020 12:46:32
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	12 Oct 2020 12:46:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:46:05
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	12 Oct 2020 12:45:41
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:45:41
Comment added 'This is not related to the cause of death.'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:38:25
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	07 Oct 2020 15:37:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:10
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:02
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 17:48:16
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	19 Nov 2020 17:48:16
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 17:48:08
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	19 Nov 2020 17:48:08

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	19 Nov 2020 17:48:08
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	19 Nov 2020 17:47:53
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	19 Nov 2020 17:47:53
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	19 Nov 2020 17:47:53
DataPoint Un-verified.	Brandy Lowman (b) (4)	19 Nov 2020 17:47:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 17:47:53
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	Brandy Lowman (b) (4)	19 Nov 2020 17:47:53
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 17:47:32
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	19 Nov 2020 13:21:13
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 13:21:13
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 13:20:54
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	19 Nov 2020 13:12:36
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Nov 2020 13:12:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:12:00
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	22 Oct 2020 13:21:24
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	12 Oct 2020 12:46:05

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	12 Oct 2020 12:46:05
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	12 Oct 2020 12:45:41
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59



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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

US3082269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Not Related (NOT RELATED)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Not Related (NOT RELATED)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:51:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 05:37:10
' (Site from DM). Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.	Ayssa Valente (b) (4) (b) (4)	15 Jan 2021 13:35:22
' answered with 'updated to N/A' (Site from DM). DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	15 Jan 2021 13:35:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	15 Jan 2021 13:35:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:58:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:49:23
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 14:48:54
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	18 Nov 2020 14:48:54
DataPoint Un-verified.	Morgan Mathis (b) (4)	18 Nov 2020 14:48:54
User entered 'None (NONE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	18 Nov 2020 14:48:54
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 14:46:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:15:17
DataPoint Un-verified.	Alice Cipollini (b) (4)	10 Nov 2020 18:15:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	10 Nov 2020 18:15:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'None (NONE)'	Erin Harrelson (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Oct 2020 15:38:33
User entered '1' reason for change: Data Entry Error	Erin Harrelson (b) (4)	07 Oct 2020 15:38:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	07 Oct 2020 15:37:59
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:06:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:51:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Jan 2021 14:22:56
DataPoint Un-verified.	(b) (4) Erin Harrelson (b) (4)	06 Jan 2021 13:03:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	06 Jan 2021 13:03:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	19 Nov 2020 17:50:29
DataPoint Un-verified.	(b) (4) Brandy Lowman (b) (4)	19 Nov 2020 17:48:24
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	19 Nov 2020 17:48:24



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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:49:28
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:11:50
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:11:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:53:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 14:54:11
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 14:53:59
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 13:07:11
DataPoint Un-verified.	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:05:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	22 Oct 2020 17:05:42
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:49:50
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:47:13
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 12:46:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 12:46:59
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:46:59
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 12:46:32
User entered empty; reason for change Data Entry Error	Brandy Lowman (b) (4) (b) (4)	12 Oct 2020 12:46:32
User entered 'Fatal (FATAL)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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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)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 17:48:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 17:48:08
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 17:47:53
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:37:59

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '0'	System	19 Nov 2020 17:48:08
User entered '1'	System	19 Nov 2020 17:47:53
User entered '0'	System	07 Oct 2020 15:37:59

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Folder: Adverse Events

Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '1'	System	07 Oct 2020 15:37:59

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:50
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
User coded data point as SOC: Cardiac disorders, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 14:54:49
Data point term sent to Coder	System	11 Mar 2021 14:54:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
Data point term sent to Coder	System	11 Mar 2021 14:52:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as SOC: Cardiac disorders, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:13:01
Data point term sent to Coder	System	19 Nov 2020 17:57:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
Data point term sent to Coder	System	19 Nov 2020 17:56:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24



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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:41:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:41:13
Data point term sent to Coder	System	07 Oct 2020 15:40:34
User entered 'New onset atrial fibrillation'	Erin Harrelson (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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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)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	07 Oct 2020 15:40:01

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:51:55
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:37:30
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated with end date' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:21:25
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:20:23
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:20:23



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 23:25:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 17:30:51
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:51:58
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	18 Jan 2021 14:21:16
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	18 Jan 2021 14:21:16
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	18 Jan 2021 14:20:23
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Jan 2021 14:20:23
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Jan 2021 14:20:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 17:30:51
User entered '03 Oct 2020'	Erin Harrelson (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	System	07 Oct 2020 15:40:01

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Grade 4 (Grade 4)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 10:03:21
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' This answered with 'This was not the cause of death. This was AE leading up to the SAE. ' (Site from System).	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:36
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	07 Oct 2020 15:40:01
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01



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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Not Related (NOT RELATED)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'Not Related (NOT RELATED)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:55:46
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 14:42:02
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 14:42:02
DataPoint Un-verified.	Brandy Lowman (b) (4) (b) (4)	24 Nov 2020 14:42:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	24 Nov 2020 14:42:02
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 14:28:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	19 Nov 2020 13:11:14
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 13:11:14
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	19 Nov 2020 13:09:39
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	19 Nov 2020 13:08:57
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 13:08:57
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 14:46:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:15:33
DataPoint Un-verified.	Alice Cipollini (b) (4)	10 Nov 2020 18:15:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	10 Nov 2020 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered 'l'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered '0'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	18 Jan 2021 14:21:16
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:21:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User closed query 'Per CDM: Per eCCGs only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:53:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Outcome](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per eCCGs only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please reconcile.' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4)	20 Oct 2020 17:31:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Per eCCGs only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please reconcile.' (Site from DM).	Erin Harrelson (b) (4)	20 Oct 2020 17:30:51
User entered 'Fatal (FATAL)'	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 14:27:36
	Erin Harrelson (b) (4)	07 Oct 2020 15:40:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	18 Jan 2021 14:22:15
User entered 'patient died from complications of fatal SAE' reason for change: Data Entry Error	Ayssa Valente (b) (4)	18 Jan 2021 14:22:15
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	18 Jan 2021 14:21:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
	Erin Harrelson (b) (4)	07 Oct 2020 15:40:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:21:24
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '0'	System	07 Oct 2020 15:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User entered '1'	System	07 Oct 2020 15:40:01

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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)	30 Apr 2021 19:30:56
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:01:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 14:54:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 14:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 17:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Nov 2020 17:56:16



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:06:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per ETRTR: Please ensure update for Concomitant Procedure for SAE "Pneumoperitoneum, presumed intra-abdominal perforation". If not Concomitant procedure to report, update SAE CRF Concomitant Procedure data point, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:59:05
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:53:44
Query 'Per ETRTR: Please ensure update for Concomitant Procedure for SAE "Pneumoperitoneum, presumed intra-abdominal perforation". If not Concomitant procedure to report, update SAE CRF Concomitant Procedure data point, thanks.' answered with 'Con Procedures have been added from the medical records.' (Site from CRA).	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:55:48
User opened query 'Per ETRTR: Please ensure update for Concomitant Procedure for SAE "Pneumoperitoneum, presumed intra-abdominal perforation". If not Concomitant procedure to report, update SAE CRF Concomitant Procedure data point, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 15:43:40
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:36:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:40:45
Data point term sent to Coder	System	21 Sep 2020 17:39:16
User entered 'Tamsulosin'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Urinary retention'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0.4'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once daily (QD)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'UN UNK 2019'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:39:01



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '804 (804)'	System	21 Sep 2020 17:39:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:32:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:32:46
Data point term sent to Coder	System	21 Sep 2020 17:41:20
User entered 'Colchicine'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Gout (both feet)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0.6'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'as needed (PRN)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'UN UNK 2018'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:40:31

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:43:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:43:45
Data point term sent to Coder	System	21 Sep 2020 17:42:22
User entered 'Tadalafil'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Erectile Dysfunction'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '2.5'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'as needed (PRN)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'UN UNK 2019'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	21 Sep 2020 17:41:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Nov 2020 17:56:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Nov 2020 17:56:13
Data point term sent to Coder	System	27 Nov 2020 15:03:50
Coding entries removed.	Morgan Mathis (b) (4)	27 Nov 2020 15:03:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 06:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 06:04:27
Data point term sent to Coder	System	06 Oct 2020 18:18:48
User entered 'Albumin (Human) 5%'	Erin Harrelson (b) (4)	06 Oct 2020 18:17:54



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:09:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'HAS BEEN UPDATED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:03:28
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:03:21
User entered 'SHOCK R/T SAE #1' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:03:21
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:12:03
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Infection preventative'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '25'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'g (g)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Un-verified.	(b) (4) Alice Cipollini (b) (4)	07 Dec 2020 13:43:19
User entered 'once daily (QD)' reason for change:	(b) (4) Alice Cipollini (b) (4)	07 Dec 2020 13:43:19
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 10:20:21
Query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' answered with 'Updated.' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:43:28
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:43:19
User entered empty; reason for change Data Entry Error	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:43:19
User opened query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:25:37
User closed query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:23:12
Query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify.' answered with 'Frequency twice is not in the drop down field.' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	04 Dec 2020 15:07:08
User opened query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:11:40
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'twice'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:40:40
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 13:42:07
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 13:41:52
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 13:41:52
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:11:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	07 Dec 2020 13:43:19
User entered empty.	System	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	07 Dec 2020 13:43:19
User entered empty.	System	06 Oct 2020 18:17:54



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '804 (804)'	System	07 Dec 2020 13:43:19
User entered empty.	System	06 Oct 2020 18:17:54

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
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) (b) (4)	06 Oct 2020 22:37:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:37:19
Data point term sent to Coder	System	06 Oct 2020 18:21:54
User entered 'Aspirin'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Abdominal pain'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '162'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:40:58
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'updated to no' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:32:43
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:32:22
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:32:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:12:41



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:21:19

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: OTHER CARDIAC STIMULANTS, PRODUCT: ATROPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 14:02:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 14:02:39
Data point term sent to Coder Coding entries removed.	System Ayssa Valente (b) (4)	01 Feb 2021 13:58:19 01 Feb 2021 13:57:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: OTHER CARDIAC STIMULANTS, PRODUCT: ATROPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 13:57:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 13:57:27
Data point term sent to Coder Coding entries removed.	System Ayssa Valente (b) (4)	01 Feb 2021 13:56:18 01 Feb 2021 13:55:48
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: OTHER CARDIAC STIMULANTS, PRODUCT: ATROPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Oct 2020 22:43:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Oct 2020 22:43:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Oct 2020 18:22:56
User entered 'Atropine'	Erin Harrelson (b) (4)	06 Oct 2020 18:22:23
	(b) (4)	

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' answered with 'updated to YEs' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:37:49
Query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' answered with 'updated to YEs' (Site from DM).	Ayssa Valente (b) (4)	01 Feb 2021 13:57:41
DataPoint Un-verified.	(b) (4)	
DataPoint Un-verified.	Ayssa Valente (b) (4)	01 Feb 2021 13:52:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	01 Feb 2021 13:52:22
User opened query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 00:55:56
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4)	06 Oct 2020 18:22:23
User entered 'No (N)'	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
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 so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:09:58
Query 'Per DM CLR: Please review and veirfy if this can be updated to NO as there is a corresponding AE condition recorded. If yes, please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:02:21
User opened query 'Per DM CLR: Please review and veirfy if this can be updated to NO as there is a corresponding AE condition recorded. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:02:17
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 so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated with appropriate indication' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:58:11
User entered 'atrial fibrillation' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:57:54
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:55:48
User entered 'bradycardia' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:55:48
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 so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 00:53:03



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:28:08
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE #1' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 14:59:14
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:15:41
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Blood pressure'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0.5'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:41:30
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'UPDATED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:11:12
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:10:49
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:10:49
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:14:38

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:22:23



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:22:23

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Feb 2021 15:40:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:40:29
Data point term sent to Coder Coding entries removed.	System Ayssa Valente (b) (4)	01 Feb 2021 13:59:19 01 Feb 2021 13:58:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 13:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 13:15:44
Data point term sent to Coder User entered 'Diltiazem (cardizem)'	System Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:25:03 06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Ayssa Valente (b) (4)	01 Feb 2021 13:58:34
DataPoint Un-verified.	Ayssa Valente (b) (4)	01 Feb 2021 13:58:26
User entered 'atrial fibrillation' reason for change: Data Entry Error	Ayssa Valente (b) (4)	01 Feb 2021 13:58:26
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:28:42
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE #1' (Site from DM).	Morgan Mathis (b) (4)	27 Nov 2020 14:59:42
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:16:33
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Blood pressure'	Erin Harrelson (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '30'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:28:36
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:50:46
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:50:38
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:50:38
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:16:15



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:24:52

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Feb 2021 15:25:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:25:28
Data point term sent to Coder Coding entries removed.	System Ayssa Valente (b) (4)	01 Feb 2021 13:59:19 01 Feb 2021 13:58:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 13:15:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 13:15:07
Data point term sent to Coder User entered 'Diltiazem (cardizem)'	System Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:27:07 06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	01 Feb 2021 13:58:45
User entered 'atrial fibrillation' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	01 Feb 2021 13:58:45
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:41:08
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE #1' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:00:20
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:17:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Blood pressure'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '10'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:41:14
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:56:54
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:56:46
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:56:46
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:17:36

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:26:18

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ETOMIDATE, PRODUCTSYNONYM: AMIDATE [ETOMIDATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 18:55:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 18:55:25
Data point term sent to Coder Coding entries removed.	System	25 Nov 2020 16:12:52
	Morgan Mathis (b) (4)	25 Nov 2020 16:12:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ETOMIDATE, PRODUCTSYNONYM: AMIDATE [ETOMIDATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 14:04:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 14:04:22
Data point term sent to Coder	System	06 Oct 2020 18:29:09
User entered 'Etomidate (amidate)'	Erin Harrelson (b) (4)	06 Oct 2020 18:28:16



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
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)	26 Nov 2020 07:43:14
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. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:12:27
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:12:21
User entered 'ANAESTHETIC FOR SAE' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:12:21
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)	25 Nov 2020 12:19:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Anaesthetic'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '20'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for a procedure. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:41:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for a procedure. Please verify if this should be updated to "No".' answered with 'UPDATED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:13:07
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:12:58
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:12:58
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for a procedure. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:18:29
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:28:16



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:28:16

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:21:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:21:17
Data point term sent to Coder	System	06 Oct 2020 18:30:11
User entered 'FENTANYL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Abdominal pain'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '50'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'ug (ug)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:43:34
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'UPDATED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:13:32
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:13:24
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	25 Nov 2020 16:13:24
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:27:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:29:55

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:29:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:29:35
Data point term sent to Coder Coding entries removed.	System Ayssa Valente (b) (4)	01 Feb 2021 13:52:16 01 Feb 2021 13:51:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:38
Data point term sent to Coder	System	06 Oct 2020 18:31:14
User entered 'Iopamidol 76%'	Erin Harrelson (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
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) (4), (b) (6)	17 Feb 2021 21:10:41
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 indication to reflect underlying condition' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:51:59
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:51:40
User entered 'CT IMAGING CONTRAST / used to diagnose pneumoperitoneum' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	01 Feb 2021 13:51:40
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)	01 Feb 2021 00:53:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Imaging contrast'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '100'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given as imaging contrast. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:41:42
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given as imaging contrast. Please verify if this should be updated to "No".' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:19
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:13
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:13
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given as imaging contrast. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:29:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:31:13

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
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) (b) (4)	09 Oct 2020 13:45:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:45:28
Data point term sent to Coder	System	06 Oct 2020 18:33:19
User entered 'lactated ringers bolus'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:42:04
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:02:22
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:02:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:02:11
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:30:12
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'replacing fluids/electrolytes'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS/ELECTROLYTES. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:42:10
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS/ELECTROLYTES. Please verify if this should be updated to "No".' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:33
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:26
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:51:26
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS/ELECTROLYTES. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:29:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:33:08

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:33:08



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:31
Data point term sent to Coder	System	06 Oct 2020 18:40:31
User entered 'Norepinephrine'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 07:42:36
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE#1' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:16:33
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:33:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'blood pressure'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '16/250'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:42:42
Query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' answered with 'Frequency is not in the drop down field' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	04 Dec 2020 15:08:15
User opened query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:12:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'three times'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:42:45
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:08
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:03
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:03
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:33:01

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:40:24



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:40:24

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 19:18:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 19:18:13
Data point term sent to Coder	System	06 Oct 2020 18:44:41
User entered 'Phenylephrine 0.9%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 07:43:10
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE#1' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:22:38
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:34:12
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Blood pressure'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '80/250'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:42:36
Query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' answered with 'Frequency not in drop down field' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	04 Dec 2020 15:09:31
User opened query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:13:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'three times'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:43:16
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:34
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:18
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:18
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:33:56

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:44:29

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Nov 2020 18:11:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Nov 2020 18:11:11
Data point term sent to Coder	System	27 Nov 2020 15:13:55
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:13:17
Coding entries removed.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:13:17
User entered 'PIPERACILLIN-TAZOBACTAM-Dextris (ZOSYN)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:13:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 19:21:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 19:21:32
Data point term sent to Coder	System	06 Oct 2020 18:46:47
User entered 'Piperacillin-tazobactam'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Infection preventative'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 07:48:19
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'Per records dosage is correct' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 15:13:29
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:35:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '3.375'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'g (g)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:43:43
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' answered with 'updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:57:23
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:49
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:52:49
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:34:58
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:45:58

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:45:58



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:49:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:49:25
Data point term sent to Coder	System	06 Oct 2020 18:47:49
User entered 'Rocuronium'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
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) (4), (b) (6)	30 Nov 2020 07:48:34
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 'RELATED TO SAE#1 AND CONCOMITANT PROCEDURES' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:25:06
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)	25 Nov 2020 12:42:14
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Paralytic'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '100'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:48:38
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:37
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:29
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:29
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:41:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:47:04



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:47:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:40
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
Data point term sent to Coder	System	06 Oct 2020 18:48:50
User entered 'Sodium bicarbonate 8.4%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:10
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:57:47
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:57:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:57:41
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:44:15
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'electrolyte replacement'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '100/1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mEq/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:15
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' answered with 'Updated.' (Site from DM).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:53
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:46
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	27 Nov 2020 14:53:46
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:48:34

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:41
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
Data point term sent to Coder	System	06 Oct 2020 18:50:56
User entered 'Sodium Bicarbonate 8.4%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:40
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:17
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:06
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:45:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'electrolyte replacement'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '150/1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mEq/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:44
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:15
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:06
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:06
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:44:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:50:04

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:10:41
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
Data point term sent to Coder	System	06 Oct 2020 18:51:57
User entered 'Sodium Bicarbonate 8.4%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:55
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:33
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:28
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:45:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'electrolyte replacement'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '50/1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mEq/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:38
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:28
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:28
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:45:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:51:09



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:51:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:09:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:09:36
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
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 BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:33
Data point term sent to Coder	System	06 Oct 2020 18:52:58
User entered 'Sodium Bicarbonate 5%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:50:25
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:55
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:46
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:46:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'electrolyte replacement'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Un-verified.	(b) (4) Alice Cipollini (b) (4)	07 Dec 2020 13:48:36
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) Alice Cipollini (b) (4)	07 Dec 2020 13:48:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:54:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 10:21:07
Query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:48:43
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:48:36
User entered empty; reason for change Data Entry Error	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 13:48:36
User opened query 'Per CDM re-query: Response noted; however, please review if this can be recorded as per day (e.g. daily once or daily twice). Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:26:08
User closed query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:26:02
Query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' answered with 'Frequency is not in drop down field' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	04 Dec 2020 15:09:00
User opened query 'Per CDM: Kindly check if frequency can be selected from frequency field and remove it from other else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:14:00
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'twice'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:50:28
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:53
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:46
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:58:46
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for ELECTROLYTE REPLACEMENT. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:46:12
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:52:25



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	07 Dec 2020 13:48:36
User entered empty.	System	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	System	07 Dec 2020 13:48:36
User entered empty.	System	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '804 (804)'	System	07 Dec 2020 13:48:36
User entered empty.	System	06 Oct 2020 18:52:25

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
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: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:17:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:17:54
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
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: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:33:34
Data point term sent to Coder	System	06 Oct 2020 18:53:59
User entered 'Sodium Chloride 0.9%'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:50:34
Query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:15
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:07
User opened query 'Per DM CLR: Please consider updating "Prophylaxis" to "Yes" as this medication is not being given to treat a specific condition. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:47:09
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Replacing fluids'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:50:36
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS. Please verify if this should be updated to "No".' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:13
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:07
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given for REPLACING FLUIDS. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:46:54
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:53:12

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:37:38
Data point term sent to Coder	System	06 Oct 2020 18:55:01
User entered 'Vancomycin'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Infection prevention'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '1000'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:51:06
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:28
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:24
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:24
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the medication was given prophylactically. Please verify if this should be updated to "No".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:47:39
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:54:10

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:36:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:36:29
Data point term sent to Coder	System	06 Oct 2020 18:56:02
User entered 'Vasopressin'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 07:51:14
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'RELATED TO SAE #1' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	27 Nov 2020 15:22:58
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:48:14
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Blood pressure'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '100/100'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'IU/mL'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Intravenous (INTRAVENOUS)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09



US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:51:24
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:49
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:43
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	27 Nov 2020 14:59:43
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not included in the list of SARs (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body) according to Protocol. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:48:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:54:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:55:09



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:55:09

US3082269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:06:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered empty.	System	06 Oct 2020 18:55:09

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:06:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:54:53
User entered 'Yes (Y)'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:31:29

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered '2 Oct 2020'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:32:30

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'CT angiogram of the chest'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:32:30

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Adverse Event (AE)'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:32:30

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:06:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered empty.	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:32:30

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered '2 Oct 2020'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:35:25



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Chest x-ray'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:35:25

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Adverse Event (AE)'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:35:25

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:06:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered empty.	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:35:25

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered '2 Oct 2020'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:02

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Central Line placement'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:02

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Adverse Event (AE)'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:02

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:06:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered empty.	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:02

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered '2 Oct 2020'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:14



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Intubation'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:14

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered 'Adverse Event (AE)'	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:14

US3082269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:06:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:04
User entered empty.	Megan Marles (b) (4) (b) (4)	13 Oct 2020 14:40:14

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:53
DataPoint Un-verified.	Morgan Mathis (b) (4)	05 Nov 2020 13:41:17
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	05 Nov 2020 13:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:55:54
User entered '21 Sep 2020'	Erin Harrelson (b) (4)	07 Oct 2020 15:41:38
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:53
User closed query 'Per CDM re-query: As per the CCG page no. 42 (V2.0), please record death as primary reason for dosing discontinuation. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:59:57
Query 'Per CDM re-query: As per the CCG page no. 42 (V2.0), please record death as primary reason for dosing discontinuation. Thank you.' answered with 'Updated.' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	24 Nov 2020 14:29:08
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	24 Nov 2020 14:28:49
User opened query 'Per CDM re-query: As per the CCG page no. 42 (V2.0), please record death as primary reason for dosing discontinuation. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:26:54
User closed query 'Per CDM: please consider selecting DEATH and make appropriate updates ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:24:57
Query 'Per CDM: please consider selecting DEATH and make appropriate updates ' answered with 'SAE includes death in description. Primary reason does not need update.' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	23 Nov 2020 13:58:15
User opened query 'Per CDM: please consider selecting DEATH and make appropriate updates ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:01:15
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:11:14
User entered 'Death (DEATH)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:09:39
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:08:57
User closed query 'Per CDM: per sponsor review, it appears the reason for dosing discontinuation and study discontinuation are not the same as they occurred on the same date (03OCT2020). Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:50:30

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Per CDM: per sponsor review, it appears the reason for dosing discontinuation and study discontinuation are not the same as they occurred on the same date (03OCT2020). Please reconcile and update accordingly.' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 14:46:42
User entered 'Death (DEATH)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 14:46:33
User opened query 'Per CDM: per sponsor review, it appears the reason for dosing discontinuation and study discontinuation are not the same as they occurred on the same date (03OCT2020). Please reconcile and update accordingly.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 09:52:32
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:42:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:55:54
User entered 'Death (DEATH)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:41:38

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:58:53
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:29:02
User entered empty; reason for change Data Entry Error	Brandy Lowman (b) (4) (b) (4)	24 Nov 2020 14:29:02
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:28:49
User closed query 'Per DM (re-query): Response noted,however data is not entered.Kindly consider to record AE number. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:14:42
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:11:14
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:09:39
Query 'Per DM (re-query): Response noted,however data is not entered.Kindly consider to record AE number. Thank you.' answered with 'ae # has been recorded' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 13:09:23
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:08:57

US3082269

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:08:30
User entered 'AE #1 Intra abdominal perforation' reason for change: Data Entry Error	Ayssa Valente (b) (4)	19 Nov 2020 13:08:30
User opened query 'Per DM (re-query): Response noted,however data is not entered.Kindly consider to record AE number. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:51:55
User closed query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:51:55
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	18 Nov 2020 14:46:33
Query 'Per CDM: per sponsor review, please indicate AE record number.' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4)	18 Nov 2020 14:45:59
User entered 'USA-US114-2020-MRNA-1273-P301000003' reason for change: Data Entry Error	Morgan Mathis (b) (4)	18 Nov 2020 14:45:48
User opened query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:52:34
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 13:42:37
User entered 'INTRA-ABDOMINAL PERFORATION' reason for change: Data Entry Error	Morgan Mathis (b) (4)	05 Nov 2020 13:42:37
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 13:41:47
DataPoint Un-verified.	Morgan Mathis (b) (4)	05 Nov 2020 13:41:47
User entered 'SAE- ATRIAL FIBRILATION' reason for change: Data Entry Error	Morgan Mathis (b) (4)	05 Nov 2020 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:55:54



US3082269

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:46

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

Audit	User	Time (GMT)
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:41:38

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered 'Death (DEATH)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

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 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
Query 'Per CDM: per CCGs please provide the record number instead of details.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:43:44
User opened query 'Per CDM: per CCGs please provide the record number instead of details.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:26:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered 'Adverse event (ADVERSE EVENT)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered empty.	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered '03 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29

US3082269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:46

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:56:33
User entered 'Unknown (UNK)'	Erin Harrelson (b) (4) (b) (4)	07 Oct 2020 15:43:29



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Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
User entered '06/Oct/2020 12:57'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

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Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
User entered '16/Oct/2020 14:29'	System	16 Oct 2020 14:29:47

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:20:57
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:17:20
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:29:47

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:57:59
User entered '23/Oct/2020 12:21'	System	23 Oct 2020 16:21:31

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:01:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:58:00
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 16:21:31

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:54
User entered '06/Nov/2020 19:01'	System	06 Nov 2020 19:01:47

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:06:38
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 19:01:47



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:54
User entered '11/Nov/2020 11:06'	System	11 Nov 2020 16:06:55

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:54
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:28:07
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:06:55

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:54
User entered '16/Nov/2020 14:28'	System	16 Nov 2020 19:28:21

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 01:38:56
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:54
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 19:28:21

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:30
User entered '21/Nov/2020 01:39'	System	21 Nov 2020 01:39:11

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 16:27:14
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:30
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 01:45:51
User entered '1'	(b) (4), (b) (6)	21 Nov 2020 01:39:11

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:31:57
User entered '12/Mar/2021 11:27'	System	12 Mar 2021 16:27:35

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 16:05:15
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:31:57
User entered '1'	(b) (4), (b) (6)	12 Mar 2021 16:27:35



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'USA-US114-2020-MRNA-1273-P301000003'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'No (N)'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Yes (Y)'	System	06 Oct 2020 12:57:08



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Barton'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Williams'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'Wilmington'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered 'NC'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:57:35
User entered '28403'	System	06 Oct 2020 12:57:08

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:17:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 14:29:36
User entered 'US'	System	06 Oct 2020 12:57:42

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '9'	System	22 Apr 2021 16:05:38
User entered '8'	System	12 Mar 2021 16:27:35
User entered '7'	System	21 Nov 2020 01:39:11
User entered '6'	System	16 Nov 2020 19:28:21
User entered '5'	System	11 Nov 2020 16:06:55
User entered '4'	System	06 Nov 2020 19:01:47
User entered '3'	System	23 Oct 2020 16:21:31
User entered '2'	System	16 Oct 2020 14:29:47
User entered '1'	System	06 Oct 2020 12:57:42



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:06:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:23:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:03:02
Data hard locked.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '22/Apr/2021 12:05'	System	22 Apr 2021 16:05:38

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:05
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:23:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:42:09
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:03:02
Data hard locked.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:39
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 16:05:38

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'USA-US114-2020-MRNA-1273-P301000006'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Barton'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Williams'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered '3806 Peachtree Ave.'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Wilmington'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'NC'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered '28403'	System	21 Nov 2020 01:50:24



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:32:13
User entered 'US'	System	12 Mar 2021 16:27:35

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'USA-US114-2020-MRNA-1273-P301000006'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'No (N)'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Barton'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Williams'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered '3806 Peachtree Ave.'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'Wilmington'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered 'NC'	System	21 Nov 2020 01:50:24

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 17:06:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:44
User entered '28403'	System	21 Nov 2020 01:50:24



US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:32:13
User entered 'US'	System	12 Mar 2021 16:27:35

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39

US3082269

Folder: SAE USA-US114-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:46

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:11:39