

US3082051 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:03:06

All time stamps listed in this document are displayed in GMT

US3082051

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

Participant ID

US3082051

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

US3082051

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

Visit date (dd MMM yyyy)	18 AUG 2020
--------------------------	-------------

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

Folder OID	SCRN
------------	------

US3082051

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3082051

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3082051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3082051

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Were any significant conditions reported?

Yes ☒
No ☐

US3082051

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	HEADACHE
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3082051

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN JAN 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3082051

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	ACUTE ENCEPHALOPATHY
Start date (dd MMM yyyy)	11 MAY 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	11 MAY 2014
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2014
Start Year (derived)	2014
Stop Month and Year (derived)	MAY 2014
Stop Year (derived)	2014

US3082051

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	ESOPHAGEAL VARICES
Start date (dd MMM yyyy)	18 JUN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3082051

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN JAN 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)	_____

US3082051

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Condition	ABDOMINAL NERVE PAIN
Start date (dd MMM yyyy)	UN JAN 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)	_____

US3082051

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:30 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:30
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	181 lb
BMI (<i>xxx.x</i>)	23.93000 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082051

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3082051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 185708

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 ☒

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Height	ND - Not Done
Weight	ND - Not Done

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3082051

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 12:28 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 12:28

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

US3082051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	12:09 (24 HR)
Collection date and time (derived)	18 AUG 2020 12:09

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:03	18 AUG 2020 12:03
Nasopharyngeal Swab 2	No		

US3082051

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:48

PC Close Date & Time

18 AUG 2020 15:18

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	18 AUG 2020 16:17
PC Open Date & Time	18 AUG 2020 16:13
PC Close Date & Time	19 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 00:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:17

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 06:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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 ☐

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

18 AUG 2020 12:48

PC Close Date & Time

18 AUG 2020 15:18

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:18

PC Open Date & Time

18 AUG 2020 16:13

PC Close Date & Time

19 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:15

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 00:04

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:05

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:18

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 06:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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 ☐

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 12:48

PC Close Date & Time

18 AUG 2020 15:18

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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 ☐

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 16:19
PC Open Date & Time	18 AUG 2020 16:13
PC Close Date & Time	19 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

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 ☒

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:16
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

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 ☒

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 00:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1423

EAB) (1725)

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:06
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 1423

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:18
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

60 of 1423

EAB) (1725)

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

Yes ☐

PC Time stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 1423

EAB) (1725)

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 06:10
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3082051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082051

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:53:02

Generated On: 09 Jun 2021 15:03:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082051

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:53:02

Generated On: 09 Jun 2021 15:03:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082051

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:53:03

Generated On: 09 Jun 2021 15:03:06

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3082051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:06

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"/>

US3082051

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:03:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3082051

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

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 _____

US3082051

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:06

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

US3082051

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:06

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

US3082051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID	USA-US114-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE PANCREATITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

78 of 1423

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

THE SUBJECT WENT TO THE
EMERGENCY ROOM WITH
ABDOMINAL PAIN, NAUSEA,
AND A FEVER. IMAGING
SHOWED POSSIBLE DISTAL
COMMON BILE DUCT STONE.
THE SUBJECT WAS ADMITTED
WITH BILIARY PANCREATITIS
WITH CHOLEDOCHOLITHIASIS,
SEPSIS, AND MASS IN LIVER.
THE PATIENT WAS STARTED
ON ANTIBIOTICS FOR SEPSIS.
AN ERCP WITH
SPHINCTEROTOMY, BALLOON
EXTRACTION, BALLOON
SWEEP, AND PD STENT
PLACEMENT WAS PERFORMED.
THE SITE WAS NOTIFIED WHEN
THE PATIENT COMPLETED HIS
DAY 15 SAFETY CALL. THE
SUBJECT REPORTED THAT HE
HAD BEEN IN THE LOCAL
HOSPITAL FOR 7 DAYS AND
WAS CURRENTLY IN THE VA
HOSPITAL. THE COORDINATOR
HAS REQUESTED HOSPITAL
MEDICAL RECORDS AND WILL
UPDATE THE EVENT AS MORE
INFORMATION BECOMES
AVAILABLE SUCH AS
MEDICATIONS GIVEN AND
DATE OF DISCHARGE. THE
PATIENT WILL NOT RECEIVE
THE SECOND DOSE OF IP PER
PRINCIPAL INVESTIGATOR.

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

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID	USA-US114-2020-MRNA-1273-P30 1000002
Adverse event	CHOLEDOCHOLITHIASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

81 of 1423

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

THE SUBJECT WENT TO THE
EMERGENCY ROOM WITH
ABDOMINAL PAIN, NAUSEA,
AND A FEVER. IMAGING
SHOWED POSSIBLE DISTAL
COMMON BILE DUCT STONE.
THE SUBJECT WAS ADMITTED
WITH BILIARY PANCREATITIS
WITH CHOLEDOCHOLITHIASIS,
SEPSIS, AND MASS IN LIVER.
THE PATIENT WAS STARTED
ON ANTIBIOTICS FOR SEPSIS.
AN ERCP WITH
SPHINCTEROTOMY, BALLOON
EXTRACTION, BALLOON
SWEEP, AND PD STENT
PLACEMENT WAS PERFORMED.
THE SITE WAS NOTIFIED WHEN
THE PATIENT COMPLETED HIS
DAY 15 SAFETY CALL. THE
SUBJECT REPORTED THAT HE
HAD BEEN IN THE LOCAL
HOSPITAL FOR 7 DAYS AND
WAS CURRENTLY IN THE VA
HOSPITAL. THE COORDINATOR
HAS REQUESTED HOSPITAL
MEDICAL RECORDS AND WILL
UPDATE THE EVENT AS MORE
INFORMATION BECOMES
AVAILABLE SUCH AS
MEDICATIONS GIVEN AND
DATE OF DISCHARGE. THE
PATIENT WILL NOT RECEIVE
THE SECOND DOSE OF IP PER
PRINCIPAL INVESTIGATOR.

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

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID

Adverse event

RIGHT POSTERIOR BENIGN
LIVER LESION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

84 of 1423

EAB) (1725)

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID	
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

86 of 1423

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

THE SUBJECT WENT TO THE
EMERGENCY ROOM WITH
ABDOMINAL PAIN, NAUSEA,
AND A FEVER. IMAGING
SHOWED POSSIBLE DISTAL
COMMON BILE DUCT STONE.
THE SUBJECT WAS ADMITTED
WITH BILIARY PANCREATITIS
WITH CHOLEDOCHOLITHIASIS,
SEPSIS, AND MASS IN LIVER.
THE PATIENT WAS STARTED
ON ANTIBIOTICS FOR SEPSIS.
AN ERCP WITH
SPHINCTEROTOMY, BALLOON
EXTRACTION, BALLOON
SWEEP, AND PD STENT
PLACEMENT WAS PERFORMED.

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)	0

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID

Adverse event

WORSENING OF ABDOMINAL
NERVE PAIN (EPIGASTRIC
ABDOMINAL PAIN)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

89 of 1423

EAB) (1725)

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

AEID	
Adverse event	WORSENING HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Feb 2021 16:52:49

Generated On: 09 Jun 2021 15:03:06

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

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

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

Yes ☒

No ☐

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

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

94 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 JUL 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MODERATE HEADACHES

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

96 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC ABDOMINAL PAIN
(AE #6)

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN (AE #6)

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

100 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	8 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication CIPROFLOXACIN HCL

Prophylaxis Yes ☐
No ☒

Indication ACUTE PANCREATITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

102 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication DUCUSATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

104 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication XARELTO

Prophylaxis Yes ☒
No ☐

Indication STROKE PREVENTION

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	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)	15 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERTROPHY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

108 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 JAN 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC ABDOMINAL
PAIN/HEADACHE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

110 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF EMBOLI

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN (AE #6)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

114 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication PROSCAR

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERTROPHY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

116 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 JAN 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NERVE PAIN [ABDOMINAL]

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

118 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	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)	15 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication IOHEXOL

Prophylaxis Yes ☐
No ☒

Indication CONTRAST FOR PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

120 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication IOPAMIDOL

Prophylaxis Yes ☐
No ☒

Indication CONTRAST FOR A PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

122 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication BACTERIAL INFECTION
(SEPSIS)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

124 of 1423

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

Name of Medication NICOTINE PATCH

Prophylaxis Yes ☒
No ☐

Indication SMOKING CESSATION

Dose per administration 1

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

If dose unit is Other, specify TRANSDERMAL PATCH

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

126 of 1423

EAB) (1725)

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 16:07:28

Generated On: 09 Jun 2021 15:03:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 AUG 2020	ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPH Y WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT.	Adverse Event	

US3082051

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

Date of dosing discontinuation (dd MMM yyyy) 8 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE#1

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Feb 2021 16:52:50

Generated On: 09 Jun 2021 15:03:06

Date of study discontinuation/completion (dd MMM yyyy) 8 SEP 2020

Reason for discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #1

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

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

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	09/SEP/2020 10:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	12/SEP/2020 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	16/SEP/2020 15:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	02/OCT/2020 13:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	26/OCT/2020 20:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	06/NOV/2020 12:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	09/NOV/2020 11:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	13/NOV/2020 17:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	19/NOV/2020 21:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Data signed: (b) (4) 19 Feb 2021 16:52:51

Generated On: 09 Jun 2021 15:03:06

SAEID	USA-US114-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	11
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3082051 (Prod: Trial Management Associates LLC - ERN - PPDS)

US3082051

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:06

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'US3082051'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:29:37

US3082051

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:04

US3082051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 16:53:03
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:29:38

US3082051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:04

US3082051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'SCRN'	System	18 Aug 2020 16:36:04

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:29:39

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '66'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'YEARS'	System	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '66'	System	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 16:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:37:28
User entered 'Male (M)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	18 Aug 2020 16:37:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 16:36:52
User entered empty.	System	18 Aug 2020 16:36:52
	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52
	(b) (4)	

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'I'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	(b) (4) Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:36:52

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Aug 2020'	System	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2020'	System	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Per CDM: Please confirm if Protocol Amendment 3 is correct, as Amendment 3 hadn't been released on Aug. 18, 2020. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 13:27:19
Query 'Per CDM: Please confirm if Protocol Amendment 3 is correct, as Amendment 3 hadn't been released on Aug. 18, 2020. ' answered with 'amendment 3 incorrect, updated to 2' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	23 Nov 2020 13:31:23
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	23 Nov 2020 13:31:18
User opened query 'Per CDM: Please confirm if Protocol Amendment 3 is correct, as Amendment 3 hadn't been released on Aug. 18, 2020. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 00:19:04
User entered 'Amendment 3 (3)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:38:15

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:29:38

US3082051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:03:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:38:40

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	15 Feb 2021 14:39:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Feb 2021 14:39:04
Data point term sent to Coder	System	15 Feb 2021 14:38:53
Coding entries removed.	Morgan Mathis (b) (4)	15 Feb 2021 14:38:02
User entered 'HEADACHE' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:38:02
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:33:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:33:37
Data point term sent to Coder	System	18 Aug 2020 18:00:55
User entered 'Moderate Headache'	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'UN Jun 2019' reason for change: Data Entry Error	Morgan Mathis (b) (4)	23 Nov 2020 15:10:24
User entered '01 Jun 2019' reason for change: Data Entry Error	Alice Cipollini (b) (4)	18 Aug 2020 18:00:55
User entered '01 Jun 2020'	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jun 2019'	System	18 Aug 2020 18:00:55
User entered 'Jun 2020'	System	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2019'	System	18 Aug 2020 18:00:55
User entered '2020'	System	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 18:00:35

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:59:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:59:59
Data point term sent to Coder	System	18 Aug 2020 18:01:56
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Alice Cipollini (b) (4)	18 Aug 2020 18:01:52
User entered 'Hperthyroidism'	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'UN Jan 2008' reason for change: Data Entry Error	Morgan Mathis (b) (4)	23 Nov 2020 15:10:43
User entered '01 Jan 2008'	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jan 2008'	System	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2008'	System	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 18:01:27

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:17:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:17:48
Data point term sent to Coder	System	10 Sep 2020 13:17:10
User entered 'Hepatitis C'	Megan Marles (b) (4)	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un Jul 2014'	Megan Marles (b) (4)	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Megan Marles (b) (4)	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	11 Sep 2020 13:22:44
User entered 'UN Oct 2014' reason for change: New Information	System	11 Sep 2020 13:22:44
Comment added 'Month of stop date is unknown.'	Brandy Lowman (b) (4)	11 Sep 2020 13:22:44
	(b) (4)	10 Sep 2020 14:52:27
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Ayssa Valente (b) (4)	10 Sep 2020 13:16:22
User entered 'un UNK 2014'	System	10 Sep 2020 13:16:22
	Megan Marles (b) (4)	10 Sep 2020 13:16:22
	(b) (4)	

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jul 2014'	System	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Oct 2014'	System	11 Sep 2020 13:22:44
User entered 'Jan 2014'	System	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:16:22

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis of liver - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:17:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:17:48
Data point term sent to Coder	System	10 Sep 2020 13:17:10
User entered 'Cirrhosis of liver'	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un UNK 2014'	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jan 2014'	System	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	10 Sep 2020 13:16:39

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Nervous system disorders, HLGT: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy acute - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:22:47
User coded data point as Term Coded data point by User (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:22:47
Data point term sent to Coder	System	10 Sep 2020 13:17:10
User entered 'Acute encephalopathy'	Megan Marles (b) (4)	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '11 May 2014'	Megan Marles (b) (4)	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Megan Marles (b) (4)	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	11 Sep 2020 13:24:52
User entered '11 May 2014' reason for change: New Information	System	11 Sep 2020 13:24:52
Comment added 'Month of stop date is unknown.'	Brandy Lowman (b) (4)	11 Sep 2020 13:24:52
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	10 Sep 2020 14:52:56
User entered 'un UNK 2014'	Ayssa Valente (b) (4)	10 Sep 2020 13:17:08
	(b) (4)	10 Sep 2020 13:17:08
	Megan Marles (b) (4)	10 Sep 2020 13:17:08
	(b) (4)	

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	11 Sep 2020 13:24:52
User entered 'Jan 2014'	System	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:17:08

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 13:18:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:18:51
Data point term sent to Coder	System	10 Sep 2020 13:18:11
User entered 'Acute renal failure'	Megan Marles (b) (4) (b) (4)	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un May 2014'	Megan Marles (b) (4)	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Megan Marles (b) (4)	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
User entered 'UN May 2014' reason for change: New Information	System	11 Sep 2020 13:27:23
Comment added 'Month of stop date is unknown.'	Brandy Lowman (b) (4)	11 Sep 2020 13:27:23
	(b) (4)	
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Ayssa Valente (b) (4)	10 Sep 2020 14:53:06
User entered 'un UNK 2014'	(b) (4)	
	System	10 Sep 2020 13:17:33
	Megan Marles (b) (4)	10 Sep 2020 13:17:33
	(b) (4)	

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	11 Sep 2020 13:27:23
User entered 'Jan 2014'	System	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:17:33

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Oesophageal varices, PT: Varices oesophageal, LLT: Esophageal varices - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:40
Data point term sent to Coder	System	10 Sep 2020 13:19:14
User entered 'Esophageal varices'	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Jun 2014'	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jun 2014'	System	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	10 Sep 2020 13:18:18

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis acute, LLT: Acute cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:40
Data point term sent to Coder	System	10 Sep 2020 13:19:13
User entered 'Acute cholecystitis'	Megan Marles (b) (4)	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un May 2014' reason for change: Data Entry Error	(b) (4)	
	Brandy Lowman (b) (4)	11 Sep 2020 13:26:40
User entered '14 May 2014'	Megan Marles (b) (4)	10 Sep 2020 13:18:42
	(b) (4)	

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Megan Marles (b) (4)	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
Comment added 'Month of stop date is unknown.'	System	11 Sep 2020 13:26:40
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Ayssa Valente (b) (4)	10 Sep 2020 14:53:23
User entered 'un May 2014'	(b) (4)	
	System	10 Sep 2020 13:18:42
	Megan Marles (b) (4)	10 Sep 2020 13:18:42
	(b) (4)	

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:18:42

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:39
Data point term sent to Coder	System	10 Sep 2020 13:19:14
User entered 'cholecystectomy'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un May 2014'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'un May 2014'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Megan Marles (b) (4)	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'May 2014'	System	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2014'	System	10 Sep 2020 13:19:06

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 14:59:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 14:59:53
Data point term sent to Coder	System	14 Dec 2020 14:58:47
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'UN Jan 2019'	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jan 2019'	System	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2019'	System	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 14:58:15

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Per CDM, DM CLR re-query on Con Med#17: Please update to reflect the location of NERVE PAIN. Review and reconcile with the Con Med page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 05:23:33
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Nerve pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 15:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 15:11:46
Data point term sent to Coder	System	22 Dec 2020 15:10:43
Query 'Per CDM, DM CLR re-query on Con Med#17: Please update to reflect the location of NERVE PAIN. Review and reconcile with the Con Med page as appropriate. ' answered with 'updated location' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	22 Dec 2020 15:10:38
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	22 Dec 2020 15:10:23
User entered 'abdominal NERVE PAIN' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	22 Dec 2020 15:10:23
User opened query 'Per CDM, DM CLR re-query on Con Med#17: Please update to reflect the location of NERVE PAIN. Review and reconcile with the Con Med page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:03:24
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Nerve pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 15:05:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 15:05:23
Data point term sent to Coder	System	14 Dec 2020 15:03:54
User entered 'NERVE PAIN'	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'UN Jan 2019'	Morgan Mathis (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'Jan 2019'	System	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '2019'	System	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 15:03:43

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '11:30'	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 11:30'	System	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '73' in	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50
DataPoint set to visible.	System	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '181' lb	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50
DataPoint set to visible.	System	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
Amendment Manager: User entered '23.93000'	System	17 Sep 2020 00:11:56
User entered '23.9'	System	18 Aug 2020 16:41:50
DataPoint set to visible.	System	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'kg/m2'	System	18 Aug 2020 16:41:50
DataPoint set to visible.	System	18 Aug 2020 16:38:25

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 08:11:58
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'COMPLETED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 12:56:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 12:56:24
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:13:44
User entered '98.3' F	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	23 Oct 2020 12:56:24
User entered 'Oral (Oral)'	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Morgan Mathis (b) (4)	23 Oct 2020 12:56:24
User entered '68'	(b) (4) Alice Cipollini (b) (4)	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'bpm'	System	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:56:24
User entered '18'	Morgan Mathis (b) (4)	18 Aug 2020 16:41:50
	(b) (4)	

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'breaths/min'	System	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:56:24
User entered '144'	Morgan Mathis (b) (4)	18 Aug 2020 16:41:50
	(b) (4)	

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:56:24
User entered '80'	Morgan Mathis (b) (4)	18 Aug 2020 16:41:50
	(b) (4)	

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 16:41:50

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:01

US3082051

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:01

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'I'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '0'	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:42:42

US3082051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:03

US3082051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:03

US3082051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:03

US3082051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'VISIT1'	System	18 Aug 2020 16:43:03

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:14:29

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:17:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:17:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 16:14:29
User entered '185708' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:14:29

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:14:29

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:38

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:38

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:38

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:38

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)' reason for change: New Information	Megan Marles (b) (4)	10 Sep 2020 13:20:27
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:43:38

US3082051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Erin Harrelson (b) (4)	22 Sep 2020 12:39:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 01:17:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:17:01

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '73' in	Morgan Mathis (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '181' lb	Morgan Mathis (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '73' in	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '181' lb	Morgan Mathis (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User accepted default value 'Pre-Dose (PREDOSE)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '11:30'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 11:30'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '98.3' F	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Oral (Oral)'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '68'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'bpm'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'breaths/min'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '144'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '80'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '73' in	Morgan Mathis (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 12:57:02
User entered '181' lb	Morgan Mathis (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User accepted default value 'Post-Dose (POSTDOSE)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 09:32:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol the vital signs are to be collected 30 minutes after dose. ' (Site from System).	Megan Marles (b) (4) (b) (4)	18 Aug 2020 18:45:58
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 18:04:37
User entered '13:00'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 13:00'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.8' F reason for change: Data Entry Error	System	18 Aug 2020 18:04:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Alice Cipollini (b) (4)	18 Aug 2020 18:04:44
User entered '97.8' (non-conformant).	(b) (4)	
	System	18 Aug 2020 18:04:37
	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37
	(b) (4)	

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Oral (Oral)'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '67'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'bpm'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'breaths/min'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '145'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '86' reason for change: Data Entry Error	Morgan Mathis (b) (4)	23 Nov 2020 15:17:22
User entered '83'	Alice Cipollini (b) (4)	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'mmHg'	System	18 Aug 2020 18:04:37

US3082051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	23 Nov 2020 15:18:09
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:18

US3082051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	23 Nov 2020 15:18:09
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:18

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '12:28'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 12:28'	System	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Left Arm (LEFT ARM)'	Alice Cipollini (b) (4)	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'ONCE'	System	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 16:44:54

US3082051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:18

US3082051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:18

US3082051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '12:09'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:18

US3082051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 12:09'	System	18 Aug 2020 16:45:18

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '18 Aug 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '12:03'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '18 Aug 2020 12:03'	System	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'No (N)'	Alice Cipollini (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 16:45:39

US3082051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	18 Aug 2020 18:05:02

US3082051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	18 Aug 2020 18:05:02

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 12:48'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 15:18'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:15:42', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb1593fa-1f3d-4171-a841-6697ba1865a0'	System	18 Aug 2020 20:17:34
User entered 'Yes (Y)'	System	18 Aug 2020 20:17:34

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:17:02', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb1593fa-1f3d-4171-a841-6697ba1865a0'	System	18 Aug 2020 20:17:34
User entered '98.3'	System	18 Aug 2020 20:17:34

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:17:08', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb1593fa-1f3d-4171-a841-6697ba1865a0'	System	18 Aug 2020 20:17:34
User entered 'No (N)'	System	18 Aug 2020 20:17:34

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:17:31', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb1593fa-1f3d-4171-a841-6697ba1865a0'	System	18 Aug 2020 20:17:34
User entered '18 Aug 2020 16:17'	System	18 Aug 2020 20:17:34

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 16:13'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 2'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:13:25', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '05c68c1f-e34b-494f-b4b3-9f71bf3af100'	System	19 Aug 2020 16:14:09
User entered 'Yes (Y)'	System	19 Aug 2020 16:14:09

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:13:36', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '05c68c1f-e34b-494f-b4b3-9f71bf3af100'	System	19 Aug 2020 16:14:09
User entered '98.1'	System	19 Aug 2020 16:14:09

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:13:44', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '05c68c1f-e34b-494f-b4b3-9f71bf3af100'	System	19 Aug 2020 16:14:09
User entered 'No (N)'	System	19 Aug 2020 16:14:09

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:14:07', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '05c68c1f-e34b-494f-b4b3-9f71bf3af100'	System	19 Aug 2020 16:14:09
User entered '19 Aug 2020 12:14'	System	19 Aug 2020 16:14:09

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 3'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:02:35', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '8f1d3222-1959-417b-8c2a-90652ad7e010'	System	21 Aug 2020 04:03:15
User entered 'Yes (Y)'	System	21 Aug 2020 04:03:15

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:02:46', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '8f1d3222-1959-417b-8c2a-90652ad7e010'	System	21 Aug 2020 04:03:15
User entered '97.5'	System	21 Aug 2020 04:03:15

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:02:54', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '8f1d3222-1959-417b-8c2a-90652ad7e010'	System	21 Aug 2020 04:03:15
User entered 'No (N)'	System	21 Aug 2020 04:03:15

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:03:09', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '8f1d3222-1959-417b-8c2a-90652ad7e010'	System	21 Aug 2020 04:03:15
User entered '21 Aug 2020 00:03'	System	21 Aug 2020 04:03:15

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 4'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:10', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'edac40b7-9237-466a-a347-2f18e3e80a62'	System	21 Aug 2020 16:04:38
User entered 'Yes (Y)'	System	21 Aug 2020 16:04:38

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:20', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'edac40b7-9237-466a-a347-2f18e3e80a62'	System	21 Aug 2020 16:04:38
User entered '98.6'	System	21 Aug 2020 16:04:38

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:25', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'edac40b7-9237-466a-a347-2f18e3e80a62'	System	21 Aug 2020 16:04:38
User entered 'No (N)'	System	21 Aug 2020 16:04:38

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:35', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'edac40b7-9237-466a-a347-2f18e3e80a62'	System	21 Aug 2020 16:04:38
User entered '21 Aug 2020 12:04'	System	21 Aug 2020 16:04:38

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 5'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:17', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb5bfedb-44f1-4d1b-8fef-7670c6ed7a42'	System	22 Aug 2020 22:17:42
User entered 'Yes (Y)'	System	22 Aug 2020 22:17:42

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:25', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb5bfedb-44f1-4d1b-8fef-7670c6ed7a42'	System	22 Aug 2020 22:17:42
User entered '98.1'	System	22 Aug 2020 22:17:42

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:29', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb5bfedb-44f1-4d1b-8fef-7670c6ed7a42'	System	22 Aug 2020 22:17:42
User entered 'No (N)'	System	22 Aug 2020 22:17:42

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:39', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'eb5bfedb-44f1-4d1b-8fef-7670c6ed7a42'	System	22 Aug 2020 22:17:42
User entered '22 Aug 2020 18:17'	System	22 Aug 2020 22:17:42

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 6'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 7'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:08:22', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6cd8ab4c-038f-44b2-b6c3-a529d3595a7c'	System	25 Aug 2020 10:09:16
User entered 'Yes (Y)'	System	25 Aug 2020 10:09:16

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:08:34', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6cd8ab4c-038f-44b2-b6c3-a529d3595a7c'	System	25 Aug 2020 10:09:16
User entered '98.3'	System	25 Aug 2020 10:09:16

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:08:39', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6cd8ab4c-038f-44b2-b6c3-a529d3595a7c'	System	25 Aug 2020 10:09:16
User entered 'No (N)'	System	25 Aug 2020 10:09:16

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:08:50', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6cd8ab4c-038f-44b2-b6c3-a529d3595a7c'	System	25 Aug 2020 10:09:16
User entered '25 Aug 2020 06:08'	System	25 Aug 2020 10:09:16

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 12:48'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 15:18'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:17:56', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'dbbf341f-313b-4f77-8177-0281a978626c'	System	18 Aug 2020 20:18:47
User entered 'None (1)'	System	18 Aug 2020 20:18:47

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:18:04', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'dbbf341f-313b-4f77-8177-0281a978626c'	System	18 Aug 2020 20:18:47
User entered 'No (N)'	System	18 Aug 2020 20:18:47

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:18:14', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'dbbf341f-313b-4f77-8177-0281a978626c'	System	18 Aug 2020 20:18:47
User entered 'No (N)'	System	18 Aug 2020 20:18:47

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:18:22', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'dbbf341f-313b-4f77-8177-0281a978626c'	System	18 Aug 2020 20:18:47
User entered 'None (1)'	System	18 Aug 2020 20:18:47

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:18:45', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'dbbf341f-313b-4f77-8177-0281a978626c'	System	18 Aug 2020 20:18:47
User entered '18 Aug 2020 16:18'	System	18 Aug 2020 20:18:47

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 16:13'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 2'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:14:33', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '121e3817-f6ea-4410-8372-08193446d140'	System	19 Aug 2020 16:15:28
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 16:15:28

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:14:39', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '121e3817-f6ea-4410-8372-08193446d140'	System	19 Aug 2020 16:15:28
User entered 'No (N)'	System	19 Aug 2020 16:15:28

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:14:50', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '121e3817-f6ea-4410-8372-08193446d140'	System	19 Aug 2020 16:15:28
User entered 'No (N)'	System	19 Aug 2020 16:15:28

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:01', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '121e3817-f6ea-4410-8372-08193446d140'	System	19 Aug 2020 16:15:28
User entered 'None (1)'	System	19 Aug 2020 16:15:28

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:22', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '121e3817-f6ea-4410-8372-08193446d140'	System	19 Aug 2020 16:15:28
User entered '19 Aug 2020 12:15'	System	19 Aug 2020 16:15:28

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 3'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:03:24', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '3b373a99-866f-458f-964d-43091190440a'	System	21 Aug 2020 04:04:29
User entered 'None (1)'	System	21 Aug 2020 04:04:29

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:03:35', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '3b373a99-866f-458f-964d-43091190440a'	System	21 Aug 2020 04:04:29
User entered 'No (N)'	System	21 Aug 2020 04:04:29

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:03:41', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '3b373a99-866f-458f-964d-43091190440a'	System	21 Aug 2020 04:04:29
User entered 'No (N)'	System	21 Aug 2020 04:04:29

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:03:54', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '3b373a99-866f-458f-964d-43091190440a'	System	21 Aug 2020 04:04:29
User entered 'None (1)'	System	21 Aug 2020 04:04:29

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:04:26', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '3b373a99-866f-458f-964d-43091190440a'	System	21 Aug 2020 04:04:29
User entered '21 Aug 2020 00:04'	System	21 Aug 2020 04:04:29

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 4'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:18', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04398e3d-a8eb-4565-8d9f-f4921557249c'	System	21 Aug 2020 16:05:23
User entered 'None (1)'	System	21 Aug 2020 16:05:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:50', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04398e3d-a8eb-4565-8d9f-f4921557249c'	System	21 Aug 2020 16:05:23
User entered 'No (N)'	System	21 Aug 2020 16:05:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:04:57', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04398e3d-a8eb-4565-8d9f-f4921557249c'	System	21 Aug 2020 16:05:23
User entered 'No (N)'	System	21 Aug 2020 16:05:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:08', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04398e3d-a8eb-4565-8d9f-f4921557249c'	System	21 Aug 2020 16:05:23
User entered 'None (1)'	System	21 Aug 2020 16:05:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:22', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04398e3d-a8eb-4565-8d9f-f4921557249c'	System	21 Aug 2020 16:05:23
User entered '21 Aug 2020 12:05'	System	21 Aug 2020 16:05:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 5'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:53', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'c8b1fa6f-64f0-4a7d-aa84-c77592b68df9'	System	22 Aug 2020 22:18:23
User entered 'None (1)'	System	22 Aug 2020 22:18:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:17:58', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'c8b1fa6f-64f0-4a7d-aa84-c77592b68df9'	System	22 Aug 2020 22:18:23
User entered 'No (N)'	System	22 Aug 2020 22:18:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:02', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'c8b1fa6f-64f0-4a7d-aa84-c77592b68df9'	System	22 Aug 2020 22:18:23
User entered 'No (N)'	System	22 Aug 2020 22:18:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:11', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'c8b1fa6f-64f0-4a7d-aa84-c77592b68df9'	System	22 Aug 2020 22:18:23
User entered 'None (1)'	System	22 Aug 2020 22:18:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:21', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'c8b1fa6f-64f0-4a7d-aa84-c77592b68df9'	System	22 Aug 2020 22:18:23
User entered '22 Aug 2020 18:18'	System	22 Aug 2020 22:18:23

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 6'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 7'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:08:58', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '0bce12c4-83ed-4c76-aeac-71ac07d7b4a5'	System	25 Aug 2020 10:09:24
User entered 'None (1)'	System	25 Aug 2020 10:09:24

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:03', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '0bce12c4-83ed-4c76-aeac-71ac07d7b4a5'	System	25 Aug 2020 10:09:24
User entered 'No (N)'	System	25 Aug 2020 10:09:24

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:08', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '0bce12c4-83ed-4c76-aeac-71ac07d7b4a5'	System	25 Aug 2020 10:09:24
User entered 'No (N)'	System	25 Aug 2020 10:09:24

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:15', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '0bce12c4-83ed-4c76-aeac-71ac07d7b4a5'	System	25 Aug 2020 10:09:24
User entered 'None (1)'	System	25 Aug 2020 10:09:24

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:22', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '0bce12c4-83ed-4c76-aeac-71ac07d7b4a5'	System	25 Aug 2020 10:09:24
User entered '25 Aug 2020 06:09'	System	25 Aug 2020 10:09:24

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 12:48'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 15:18'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:00', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:04', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:09', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:14', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:18', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:26', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'None (0)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:38', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered 'No (N)'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-18T16:19:48', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '6fc6f9ad-6f64-4b75-9cb1-d36aba329406'	System	18 Aug 2020 20:19:52
User entered '18 Aug 2020 16:19'	System	18 Aug 2020 20:19:52

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '18 Aug 2020 16:13'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 2'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:34', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'None (0)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:44', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'No interference with activity (1)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:50', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'None (0)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:15:56', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'None (0)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:16:01', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'None (0)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:16:06', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'None (0)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:16:17', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered 'No (N)'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-19T12:16:32', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'ecd878f9-a80f-49e7-b3ff-34b3130abc27'	System	19 Aug 2020 16:16:35
User entered '19 Aug 2020 12:16'	System	19 Aug 2020 16:16:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 3'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:04:36', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:04:47', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:04:53', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:04:57', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:05:02', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:05:09', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'None (0)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:05:21', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered 'No (N)'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T00:05:36', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: 'a70c7a2e-612f-4b1f-a1de-dedfc0f9d87e'	System	21 Aug 2020 04:05:39
User entered '21 Aug 2020 00:05'	System	21 Aug 2020 04:05:39

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 4'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:29', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'None (0)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:33', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'None (0)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:37', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'None (0)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:41', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'None (0)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:45', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f' User entered 'None (0)'	System	21 Aug 2020 16:06:06
	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:48', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'None (0)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:05:53', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered 'No (N)'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-21T12:06:05', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '04672a39-0abb-427a-89c9-334ca921d01f'	System	21 Aug 2020 16:06:06
User entered '21 Aug 2020 12:06'	System	21 Aug 2020 16:06:06

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 5'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:27', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:30', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:34', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:37', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:41', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:44', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'None (0)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:51', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered 'No (N)'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-22T18:18:58', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '1e9d30b7-55d5-4992-b97d-24821ba7bbd3'	System	22 Aug 2020 22:19:03
User entered '22 Aug 2020 18:18'	System	22 Aug 2020 22:19:03

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 6'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
Data entry locked.	System	18 Aug 2020 16:44:54
User entered 'Day 7'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:47', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:51', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:09:56', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:10:02', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:10:16', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:10:21', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'None (0)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

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 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:10:26', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered 'No (N)'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c15b38407c36e246)', Time: '2020-08-25T06:10:31', User OID: 'PatientReportedOutcome (US3082051)', ODM File OID: '17ecd42e-5737-452c-95a8-4f0d92137f8d'	System	25 Aug 2020 10:10:35
User entered '25 Aug 2020 06:10'	System	25 Aug 2020 10:10:35

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:44:54

US3082051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:33:40
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:44:54

US3082051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	25 Aug 2020 13:31:58

US3082051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '25 Aug 2020'	Ayssa Valente (b) (4)	25 Aug 2020 13:31:58

US3082051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Contact Made (CONTACT MADE)'	Ayssa Valente (b) (4)	25 Aug 2020 13:31:58

US3082051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Ayssa Valente (b) (4)	25 Aug 2020 13:31:58

US3082051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	25 Aug 2020 13:32:04

US3082051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	25 Aug 2020 13:32:04

US3082051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Angie Northcott (b) (4)	01 Sep 2020 13:21:54

US3082051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '1 Sep 2020'	Angie Northcott (b) (4)	01 Sep 2020 13:21:54

US3082051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4)	01 Sep 2020 13:21:54

US3082051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Angie Northcott (b) (4)	01 Sep 2020 13:21:54

US3082051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Angie Northcott (b) (4)	01 Sep 2020 13:21:59

US3082051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	01 Sep 2020 13:21:59

US3082051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	08 Sep 2020 16:23:34

US3082051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered '8 Sep 2020'	Alice Cipollini (b) (4)	08 Sep 2020 16:23:34

US3082051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered 'Contact Made (CONTACT MADE)'	Alice Cipollini (b) (4)	08 Sep 2020 16:23:34

US3082051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User entered empty.	Alice Cipollini (b) (4)	08 Sep 2020 16:23:34

US3082051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:53:03
User closed query 'Per CDM: Please note as per End of Study / Study Discontinuation form the participant is not continuing to the next visit. Please update this field accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:16:03
Query 'Per CDM: Please note as per End of Study / Study Discontinuation form the participant is not continuing to the next visit. Please update this field accordingly. ' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	28 Oct 2020 11:45:23
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	28 Oct 2020 11:45:17
User opened query 'Per CDM: Please note as per End of Study / Study Discontinuation form the participant is not continuing to the next visit. Please update this field accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:28:03
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	08 Sep 2020 16:23:40

US3082051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	28 Oct 2020 11:45:17
User entered '1'	System	08 Sep 2020 16:23:40

US3082051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:39
User entered 'Yes (Y)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:25:07

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:32
User entered 'USA-US114-2020-mRNA-1273-P301000002'	System	09 Sep 2020 14:03:23
User entered 'New'	(b) (4), (b) (6)	09 Sep 2020 14:03:23

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:02:20
User closed query 'PV Query: The event term contains multiple event terms. Please consider separating them back into separate events.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:56:43
Query 'PV Query: The event term contains multiple event terms. Please consider separating them back into separate events.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4) (b) (4)	15 Oct 2020 16:10:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:14
Data point term sent to Coder	System	15 Oct 2020 16:09:29
Query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' canceled (Site from System).	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:09:24
Data point term sent to Coder	System	15 Oct 2020 16:08:24
User entered 'ACUTE PANCREATITIS' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	15 Oct 2020 16:07:45
User opened query 'PV Query: The event term contains multiple event terms. Please consider separating them back into separate events.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:43:46

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' (Site from System).	Coder Import (b) (4)	04 Oct 2020 13:55:35
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	System	02 Oct 2020 12:40:58
	Morgan Mathis (b) (4)	02 Oct 2020 12:40:54
	(b) (4)	
Coding entries removed.	Morgan Mathis (b) (4)	02 Oct 2020 12:40:54
	(b) (4)	
User entered 'ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS' reason for change:	Morgan Mathis (b) (4)	02 Oct 2020 12:40:54
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 12:57:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 12:57:35
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 12:56:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 12:55:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 12:55:39
	(b) (4)	
Query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' canceled (Site from System).	Coder Import (b) (4)	16 Sep 2020 12:55:33
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 12:54:28
User entered 'ACUTE PANCREATITIS' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:54:09
	(b) (4)	
User opened query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' (Site from System).	Coder Import (b) (4)	11 Sep 2020 14:28:36
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 14:11:35

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Brandy Lowman (b) (4)	11 Sep 2020 14:11:22
User entered 'ACUTE PANCREATITIS w/choledocholithiasis' reason for change: Data Entry Error	Brandy Lowman (b) (4)	11 Sep 2020 14:11:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:38:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:38:36
Data point term sent to Coder	System	11 Sep 2020 13:37:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis acute, LLT: Acute pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:36:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:36:36
Query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' canceled (Site from System).	Coder Import (b) (4)	11 Sep 2020 13:36:31
Data point term sent to Coder	System	11 Sep 2020 13:36:07
User entered 'ACUTE PANCREATITIS' reason for change: Data Entry Error	Brandy Lowman (b) (4)	11 Sep 2020 13:35:20
User opened query 'For coding purposes, please split ACUTE PANCREATITIS WITH CHOLEDOCHOLITHIASIS into separate entries' (Site from System).	Coder Import (b) (4)	11 Sep 2020 11:57:30
Data point term sent to Coder	System	08 Sep 2020 17:30:41
User entered 'Acute pancreatitis with choledocholithiasis'	Megan Marles (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'Yes (Y)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '26 Aug 2020'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:02:35
DataPoint Un-verified.	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
User entered 'No (N)' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'Yes (Y)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:02:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:56:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:11:09
User entered '30 Sep 2020' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:40:59
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).		12 Oct 2020 14:39:43
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		12 Oct 2020 14:34:16
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		02 Oct 2020 13:04:49
DataPoint Un-verified.		23 Sep 2020 17:46:18
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		16 Sep 2020 13:41:25
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:50:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:50:10
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Megan Marles (b) (4)	08 Sep 2020 18:50:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Sep 2020 17:29:50
	Megan Marles (b) (4)	08 Sep 2020 17:29:50
	(b) (4)	

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'Yes (Y)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:02:57
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).	System	15 Oct 2020 16:07:45
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 by data change (Site from System).	System	15 Oct 2020 16:07:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:46:34
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 17:29:50
User entered 'I'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '26 Aug 2020'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:03:04
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:56:52
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:11:20
User entered '30 Sep 2020' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:40:34
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).		02 Oct 2020 13:04:54
DataPoint Un-verified.		23 Sep 2020 17:46:48
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		16 Sep 2020 13:41:08
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:03:08
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	15 Oct 2020 16:07:45
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).		15 Oct 2020 16:07:45
User entered 'No (N)' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:00
DataPoint Verified.		23 Sep 2020 17:45:54
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).		11 Sep 2020 13:44:50
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	11 Sep 2020 13:44:50
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	11 Sep 2020 13:42:51
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).		11 Sep 2020 13:42:51
User entered empty; reason for change Data Entry Error	Brandy Lowman (b) (4)	11 Sep 2020 13:42:51
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	08 Sep 2020 17:29:50
User entered 'Unknown (UNK)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 02:10:22
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 13:44:13
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 13:44:13
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Brandy Lowman (b) (4)	11 Sep 2020 13:44:13
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 13:43:58
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 13:43:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Brandy Lowman (b) (4)	11 Sep 2020 13:43:58
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:50:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:50:10
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:50:10
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Megan Marles (b) (4)	08 Sep 2020 18:50:10
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:50:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:50:10
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Megan Marles (b) (4) (b) (4)	08 Sep 2020 18:50:10
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:29:50
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
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).	(b) (4) System	02 Oct 2020 12:31:29
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	02 Oct 2020 12:31:29
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
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	14 Sep 2020 15:54:37
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:50:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:50:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Megan Marles (b) (4) (b) (4)	08 Sep 2020 18:50:10
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:29:50
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:35:57
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Concomitant Procedure was recorded to match the AE.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:38:28
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:59:08
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '1'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:03:26
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:56:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:11:36
DataPoint Un-verified.	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:07:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:41:42
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).		02 Oct 2020 13:04:59
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		16 Sep 2020 13:43:05
User entered 'Unknown (UNKNOWN)'	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Megan Marles (b) (4) (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'PV query: Please clarify whether examinations of COVID 19 were performed.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:11:12
Query 'PV query: Please clarify whether examinations of COVID 19 were performed.' answered with 'Reviewed procedure history, no COVID 19 examinations were recorded. ' (Site from Safety).	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:12:23
User opened query 'PV query: Please clarify whether examinations of COVID 19 were performed.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:13:57
User closed query 'Per DM CLR re-query- Per response kindly updated the appropriate eCRF if the records are available.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:08:20
User closed query 'Per DM CLR: SAE Narrative = IMAGING, SEPSIS and Mass in the liver / THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:08:18
Query 'Per DM CLR re-query- Per response kindly updated the appropriate eCRF if the records are available.' answered with 'VA only provided med list and will not provide any other records ' (Site from DM).	Erin Harrelson (b) (4)	13 Nov 2020 15:04:18
User opened query 'Per DM CLR re-query- Per response kindly updated the appropriate eCRF if the records are available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:20:04
User closed query 'Per DM CLR: SAE NARRATIVE: THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:20:04

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = IMAGING, SEPSIS and Mass in the liver / THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: SAE Narrative = IMAGING, SEPSIS and Mass in the liver / THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User closed 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). User closed query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety). User closed query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety). 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).' (Site from Safety). 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).	Flo Abbott (b) (4)	23 Oct 2020 19:38:32
	(b)	19 Oct 2020 10:32:13
	(4),	16 Oct 2020 12:57:30
	(b)	16 Oct 2020 12:57:27
	(6)	16 Oct 2020 12:57:09
		16 Oct 2020 12:57:05
		16 Oct 2020 12:57:01

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE NARRATIVE: THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Still awaiting records from the VA in Fayetteville' (Site from DM).	Flo Abbott (b) (4)	15 Oct 2020 16:19:55
Query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:19:40
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 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:19:29
Query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:19:20
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).' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:19:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:19:05

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User opened 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)	12 Oct 2020 14:44:00
User opened query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).	(b)	12 Oct 2020 14:43:27
User opened query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).	(4),	12 Oct 2020 14:43:03
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).' (Site from Safety).	(b)	12 Oct 2020 14:42:04
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).	(6)	12 Oct 2020 14:41:24
Query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' canceled (Site from Safety).		02 Oct 2020 13:05:11
Query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:05:08
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).' canceled (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:05:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:05:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

683 of 1423

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE NARRATIVE: THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:59:48
User opened query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:43:26
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).		16 Sep 2020 13:44:51
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).' (Site from Safety).		16 Sep 2020 13:43:28
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).		16 Sep 2020 13:42:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT WENT TO THE EMERGENCY ROOM WITH ABDOMINAL PAIN, NAUSEA, AND A FEVER. IMAGING SHOWED POSSIBLE DISTAL COMMON BILE DUCT STONE. THE SUBJECT WAS ADMITTED WITH BILIARY PANCREATITIS WITH CHOLEDOCHOLITHIASIS, SEPSIS, AND MASS IN LIVER. THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED. THE SITE WAS NOTIFIED WHEN THE PATIENT COMPLETED HIS DAY 15 SAFETY CALL. THE SUBJECT REPORTED THAT HE HAD BEEN IN THE LOCAL HOSPITAL FOR 7 DAYS AND WAS CURRENTLY IN THE VA HOSPITAL. THE COORDINATOR HAS REQUESTED HOSPITAL MEDICAL RECORDS AND WILL UPDATE THE EVENT AS MORE INFORMATION BECOMES AVAILABLE SUCH AS MEDICATIONS GIVEN AND DATE OF DISCHARGE.The patient will not receive the second dose of IP per principal investigator.' reason for change: Data Entry Error	Megan Marles (b) (4)	08 Sep 2020 18:51:32
User entered 'The subject went to the emergency room with abdominal pain, nausea, and a fever. Imaging showed possible distal common bile duct stone. The subject was admitted with biliary pancreatitis with choledocholithiasis, sepsis, and mass in liver. The patient was started on antibiotics for sepsis. An ERCP with sphincterotomy, balloon extraction, balloon sweep, and PD stent placement was performed. The site was notified when the patient completed his Day 15 safety call. The subject reported that he had been in the local hospital for 7 days and was currently in the VA hospital. The coordinator has requested hospital medical records and will update the event as more information becomes available such as medications given and date of discharge.'	Megan Marles (b) (4)	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	08 Sep 2020 17:29:50

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	(b) (4) Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4)	23 Sep 2020 17:45:54
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:28:24
User entered 'USA-US114-2020-mRNA-1273-P301000002' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:28:18
User entered empty.		16 Sep 2020 14:34:35

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as SOC: Hepatobiliary disorders, HLGT: Bile duct disorders, HLT: Obstructive bile duct disorders (excl neoplasms), PT: Bile duct stone, LLT: Choledocholithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:11:41
Data point term sent to Coder	System	15 Oct 2020 16:10:30
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
Data point term sent to Coder	System	02 Oct 2020 12:41:59
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User coded data point as SOC: Hepatobiliary disorders, HLGT: Bile duct disorders, HLT: Obstructive bile duct disorders (excl neoplasms), PT: Bile duct stone, LLT: Choledocholithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 12:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 12:56:37
Data point term sent to Coder	System	16 Sep 2020 12:55:28
User entered 'CHOLEDOCHOLITHIASIS'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'Yes (Y)'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'No (N)'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered 'No (N)'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:54:56
User entered '26 Aug 2020' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:54:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
User entered empty.	System	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:04:25
DataPoint Un-verified.	Flo Abbott (b) (4)	15 Oct 2020 16:14:24
User entered 'No (N)' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:14:24
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:54:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:04:26
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:57:49
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)	16 Oct 2020 12:38:40
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Flo Abbott (b) (4)	15 Oct 2020 16:15:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:14:37
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	15 Oct 2020 16:14:24
User entered '30 Sep 2020' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:14:24
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:31
DataPoint Verified.	(b) (6)	23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 14:33:32
User entered empty.	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

698 of 1423

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
User entered empty.	System	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:54:56
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:54:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:04:43
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).		16 Oct 2020 05:49:26
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)	15 Oct 2020 16:16:03
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:38
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
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	16 Sep 2020 12:55:33
User entered '1' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:55:33
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '26 Aug 2020' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:55:33
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:04:48
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		16 Oct 2020 12:57:58
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:16:12
User entered '30 Sep 2020' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:15:27
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:37
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		16 Sep 2020 14:33:18
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:04:55
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit. ' (Site from Safety).		16 Oct 2020 12:58:03
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit. ' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:16:39
User entered 'No (N)' reason for change: New Information	Flo Abbott (b) (4)	15 Oct 2020 16:16:31
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:40
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit. ' (Site from Safety).		16 Sep 2020 14:34:25
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:04:59
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:41:21
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 02:10:30
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:44
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:56:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:56:20
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	16 Sep 2020 12:56:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:56:20
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:56:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:56:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:56:20
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
DataPoint Un-verified.	Alice Cipollini (b) (4)	20 Nov 2020 16:03:59
User entered 'None (NONE)' reason for change:	(b) (4)	20 Nov 2020 16:03:59
Data Entry Error	Alice Cipollini (b) (4)	20 Nov 2020 16:03:59
DataPoint Verified.	(b) (4)	22 Oct 2020 13:05:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Flo Abbott (b) (4)	02 Oct 2020 12:41:21
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).	Morgan Mathis (b) (4)	02 Oct 2020 12:31:29
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).	(b) (4)	02 Oct 2020 12:31:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:47
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:56:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:56:20
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	16 Sep 2020 12:56:20
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:56:20

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	(b) (4) Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4)	23 Sep 2020 17:45:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 12:57:07
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 12:54:29
User entered '0'	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please review response as there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 09:25:40
Query 'Per DM CLR: Please review response as there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:08:30
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:08:21
User entered '1' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:08:21
User opened query 'Per DM CLR: Please review response as there is a Concomitant Medication (#16) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:33:49
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered '0'	Kelsey Heston (b) (4) (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR re-query: Per response if the records are available then please update the Conprocedure form else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:18:04
Query 'Per DM CLR re-query: Per response if the records are available then please update the Conprocedure form else clarify.' answered with 'VA only provided med list and will not provide any other records.' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	13 Nov 2020 15:03:50
User opened query 'Per DM CLR re-query: Per response if the records are available then please update the Conprocedure form else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:24:14
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:24:14
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Still awaiting records from the VA in Fayetteville' (Site from DM).	Flo Abbott (b) (4)	15 Oct 2020 16:18:24
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:41:21
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 22:00:39
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:57:07
User entered '0'	(b) (4) Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:05:17
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:58:07
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:17:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Flo Abbott (b) (4)	15 Oct 2020 16:17:09
Data Entry Error		
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:51
DataPoint Verified.		23 Sep 2020 17:45:54
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		16 Sep 2020 14:33:52
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:57:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 12:57:07
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:57:07
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 12:54:29
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:45:54
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'PV Query: If medications taken while hospitalized are available, please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:43:23
Query 'PV Query: If medications taken while hospitalized are available, please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Medications have already been added' (Site from Safety).	Flo Abbott (b) (4)	06 Nov 2020 18:42:24
User opened query 'PV Query: If medications taken while hospitalized are available, please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:08:26
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),	03 Nov 2020 12:41:17
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).' (Site from Safety).	(b) (6)	03 Nov 2020 12:41:16
User closed query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).		03 Nov 2020 12:41:14

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:41:09
User closed 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).		03 Nov 2020 12:41:08
Query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' answered with 'added to the adverse event log, awaiting PI assessment of changes' (Site from Safety).	Flo Abbott (b) (4)	30 Oct 2020 16:23:59
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).' answered with '3 attempts have been made to the VA in Fayetteville, they will only provide medication not a DC summary' (Site from Safety).	Flo Abbott (b) (4)	29 Oct 2020 15:48:22
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with '3 attempts have been made to the VA in Fayetteville, they will only provide medication not a DC summary' (Site from Safety).	Flo Abbott (b) (4)	29 Oct 2020 15:48:14
Query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' answered with '3 attempts have been made to the VA in Fayetteville, they will only provide medication not a DC summary' (Site from Safety).	Flo Abbott (b) (4)	29 Oct 2020 15:47:42

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
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 '3 attempts have been made to the VA in Fayetteville, they will only provide medication not a DC summary' (Site from Safety).	Flo Abbott (b) (4)	29 Oct 2020 15:47:33
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)	26 Oct 2020 21:40:10
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).' (Site from Safety).	(4),	26 Oct 2020 21:40:01
User opened query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).	(b)	26 Oct 2020 21:39:51
User opened query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).	(b)	26 Oct 2020 21:39:39
User opened 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).	(6)	26 Oct 2020 21:39:24
User closed 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).		26 Oct 2020 20:23:57
User closed query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).		26 Oct 2020 20:23:54

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 20:23:51
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).' (Site from Safety).		26 Oct 2020 20:23:48
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).		26 Oct 2020 20:23:44
Query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	23 Oct 2020 19:39:47
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 'updated' (Site from Safety).	Flo Abbott (b) (4)	23 Oct 2020 19:39:41
Query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	23 Oct 2020 19:39:34
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).' answered with 'updated' (Site from Safety).	Flo Abbott (b) (4)	23 Oct 2020 19:39:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'update' (Site from Safety).	Flo Abbott (b) (4)	23 Oct 2020 19:39:13

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User opened 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)	23 Oct 2020 17:56:53
User opened query 'PV Query: Please provide results of diagnostic tests performed (if any) in evaluation of liver mass.' (Site from Safety).	(4),	23 Oct 2020 17:56:47
User opened query 'PV Query: Please confirm if liver mass and sepsis meet criteria for separate AE/SAE reporting. If so, please report in EDC. If not, please clarify.' (Site from Safety).	(b)	23 Oct 2020 17:56:21
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).' (Site from Safety).	(6)	23 Oct 2020 17:56:13
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).		23 Oct 2020 17:56:05
DataPoint Verified.		22 Oct 2020 13:05:22
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).' (Site from Safety).		16 Oct 2020 12:58:13
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).		16 Oct 2020 12:58:10

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:18:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Still awaiting records from the VA in Fayetteville' (Site from Safety).	Flo Abbott (b) (4)	15 Oct 2020 16:18:08
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:47:54
DataPoint Verified.		23 Sep 2020 17:45:54
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).' (Site from Safety).		16 Sep 2020 14:34:06
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).		16 Sep 2020 14:33:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Sep 2020 12:57:07
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Sep 2020 12:57:07

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT WENT TO THE EMERGENCY ROOM WITH ABDOMINAL PAIN, NAUSEA, AND A FEVER. IMAGING SHOWED POSSIBLE DISTAL COMMON BILE DUCT STONE. THE SUBJECT WAS ADMITTED WITH BILIARY PANCREATITIS WITH CHOLEDOCHOLITHIASIS, SEPSIS, AND MASS IN LIVER. THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED. THE SITE WAS NOTIFIED WHEN THE PATIENT COMPLETED HIS DAY 15 SAFETY CALL. THE SUBJECT REPORTED THAT HE HAD BEEN IN THE LOCAL HOSPITAL FOR 7 DAYS AND WAS CURRENTLY IN THE VA HOSPITAL. THE COORDINATOR HAS REQUESTED HOSPITAL MEDICAL RECORDS AND WILL UPDATE THE EVENT AS MORE INFORMATION BECOMES AVAILABLE SUCH AS MEDICATIONS GIVEN AND DATE OF DISCHARGE.THE PATIENT WILL NOT RECEIVE THE SECOND DOSE OF IP PER PRINCIPAL INVESTIGATOR.' reason for change: Data Entry Error	Kelsey Heston (b) (4)	16 Sep 2020 12:57:07
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Sep 2020 12:55:33
User entered empty.	Kelsey Heston (b) (4)	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
User entered '1'	System	16 Sep 2020 12:55:33

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21
User entered '1'	System	16 Sep 2020 12:54:29

US3082051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	15 Oct 2020 16:16:31
DataPoint activated with code reason code Data required.	Flo Abbott (b) (4)	15 Oct 2020 16:09:54
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 12:41:21

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatic and biliary neoplasms benign, HLT: Hepatobiliary neoplasms benign, PT: Benign hepatic neoplasm, LLT: Benign tumor of liver - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 23:38:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:38:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
Data point term sent to Coder	System	29 Oct 2020 15:56:07
User entered 'Right Posterior Benign Liver Lesion'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Yes (Y)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '27 Aug 2020'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4)	29 Oct 2020 16:17:16
User entered 'Yes (Y)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '30 Sep 2020' reason for change: Data Entry Error	Flo Abbott (b) (4)	29 Oct 2020 16:17:16
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:23:04
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:22:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:22:51
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:22:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:22:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 15:55:28
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Not Related (NOT RELATED)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
DataPoint Un-verified.	Alice Cipollini (b) (4)	20 Nov 2020 16:03:16
User entered 'None (NONE)' reason for change:	(b) (4)	
Data Entry Error	Alice Cipollini (b) (4)	20 Nov 2020 16:03:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	02 Nov 2020 15:53:00
	(b) (4)	
User entered 'None (NONE)'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:23:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 17:22:51
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:22:51
User entered '1' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:22:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Oct 2020 15:55:28
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 16:17:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 16:17:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Flo Abbott (b) (4)	29 Oct 2020 16:17:16
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 15:55:28
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	29 Oct 2020 15:55:28

US3082051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4)	24 Nov 2020 15:53:18
Un-reviewed for Safety.	(b) (4),	23 Nov 2020 18:12:43
DataPoint Un-verified.	(b) (6)	23 Nov 2020 18:12:43
User entered empty; reason for change Data Entry Error		23 Nov 2020 18:12:43
DataPoint Verified.		17 Nov 2020 18:04:31
Reviewed for Safety.		06 Nov 2020 17:30:04
User entered 'USA-US114-2020-mRNA-1273-P301000002'		06 Nov 2020 17:29:32

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:32:30
Query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' answered with 'Per PI it is not an SAE, primary SAE was acute pancreatitis ' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	18 Nov 2020 17:02:41
User opened query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:09:24
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:36:54
Data point term sent to Coder	System	30 Oct 2020 16:19:56
User entered 'Sepsis'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Yes (Y)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '26 Aug 2020'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '26 Aug 2020'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 13:50:56
DataPoint Un-verified.	Ayssa Valente (b) (4)	05 Nov 2020 17:25:07
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:25:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
Query 'Data is required. Please complete.' answered with 'awaiting PI assessment' (Site from System).	Flo Abbott (b) (4)	30 Oct 2020 16:22:40
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:19:17
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Nov 2020 17:01:27
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Nov 2020 16:59:14
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Nov 2020 16:59:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 16:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:17
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Nov 2020 17:23:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	05 Nov 2020 17:23:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	05 Nov 2020 17:23:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:23:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Nov 2020 17:23:41
DataPoint Un-verified.	Ayssa Valente (b) (4)	05 Nov 2020 17:23:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:23:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:19:17
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Nov 2020 17:01:57
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	18 Nov 2020 17:01:57
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	18 Nov 2020 17:01:27
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
User entered '0' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
User closed query 'Per CDM re-query: Response noted however, Hospital Admission Date, Hospital Discharge Date is missing. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:21:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:52:12
Query 'Per CDM re-query: Response noted however, Hospital Admission Date, Hospital Discharge Date is missing. Please review and reconcile' answered with 'updated.' (Site from DM).	Brandy Lowman (b) (4)	09 Nov 2020 14:18:01
User opened query 'Per CDM re-query: Response noted however, Hospital Admission Date, Hospital Discharge Date is missing. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:55:38
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)	09 Nov 2020 13:54:39

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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 'corrected' (Site from System).	Flo Abbott (b) (4)	06 Nov 2020 18:58:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Nov 2020 17:23:41
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 Nov 2020 17:23:41
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 Nov 2020 17:23:41
DataPoint Un-verified.	Ayssa Valente (b) (4)	05 Nov 2020 17:23:41
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Ayssa Valente (b) (4)	05 Nov 2020 17:23:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 13:34:36
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	30 Oct 2020 16:19:17
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
User entered empty; reason for change Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:52:19
DataPoint Un-verified.	Brandy Lowman (b) (4)	09 Nov 2020 14:17:53
User entered '26 Aug 2020' reason for change: Data Entry Error	Brandy Lowman (b) (4)	09 Nov 2020 14:17:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
User entered empty; reason for change Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 17:01:27
User closed query 'PV Query: Please verify and confirm the discharge date of the event Sepsis. As the discharge date overlaps with the hospitalized period for other events.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:28:11
Query 'PV Query: Please verify and confirm the discharge date of the event Sepsis. As the discharge date overlaps with the hospitalized period for other events.' answered with 'Confirmed. Dates are correct.' (Site from Safety).	Erin Harrelson (b) (4) (b) (4)	13 Nov 2020 15:05:28
User opened query 'PV Query: Please verify and confirm the discharge date of the event Sepsis. As the discharge date overlaps with the hospitalized period for other events.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:03:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:52:22
DataPoint Un-verified.	Brandy Lowman (b) (4)	09 Nov 2020 14:17:53
User entered '30 Aug 2020' reason for change: Data Entry Error	Brandy Lowman (b) (4)	09 Nov 2020 14:17:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:18
DataPoint Un-verified.	Ayssa Valente (b) (4)	18 Nov 2020 17:01:57
User entered empty; reason for change Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 17:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 06:03:25
DataPoint Un-verified.	Ayssa Valente (b) (4)	05 Nov 2020 17:24:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:24:45
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
Query 'Data is required. Please complete.' answered with 'Awaiting PI assessment' (Site from System).	Flo Abbott (b) (4)	30 Oct 2020 16:21:57
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:19:17
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Not Related (NOT RELATED)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:53:18
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM). Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'Updated action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:48:29
DataPoint Un-verified.	Alice Cipollini (b) (4)	20 Nov 2020 16:02:20
User entered 'None (NONE)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	20 Nov 2020 16:01:48
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:38:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Un-verified.	(b) (4)	
	Morgan Mathis (b) (4)	14 Dec 2020 15:01:04
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Morgan Mathis (b) (4)	14 Dec 2020 15:01:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:53:18
	(b) (4)	
DataPoint Un-verified.	Erin Harrelson (b) (4)	23 Nov 2020 13:10:31
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Erin Harrelson (b) (4)	23 Nov 2020 13:10:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
	(b) (4)	
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17
	(b) (4)	

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Un-verified.	(b) (4)	
	Morgan Mathis (b) (4)	14 Dec 2020 15:01:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Morgan Mathis (b) (4)	14 Dec 2020 15:01:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:53:18
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed that is indicated for this AE. Please reconcile with ConMed page and update indication of the corresponding ConMed so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:48:47
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed that is indicated for this AE. Please reconcile with ConMed page and update indication of the corresponding ConMed so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4)	23 Nov 2020 13:10:39
	(b) (4)	
DataPoint Un-verified.	Erin Harrelson (b) (4)	23 Nov 2020 13:10:31
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Erin Harrelson (b) (4)	23 Nov 2020 13:10:31
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed that is indicated for this AE. Please reconcile with ConMed page and update indication of the corresponding ConMed so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:58:44
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
	(b) (4)	
User entered '1'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17
	(b) (4)	

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:23
User closed query 'Per CDM: Per response "corrected", however there is no change reflecting in eCRF, kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:55:00
Query 'Per CDM: Per response "corrected", however there is no change reflecting in eCRF, kindly review and update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	12 Nov 2020 13:01:31
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	12 Nov 2020 13:01:23
User entered 'THE SUBJECT WENT TO THE EMERGENCY ROOM WITH ABDOMINAL PAIN, NAUSEA, AND A FEVER. IMAGING SHOWED POSSIBLE DISTAL COMMON BILE DUCT STONE. THE SUBJECT WAS ADMITTED WITH BILIARY PANCREATITIS WITH CHOLEDOCHOLITHIASIS, SEPSIS, AND MASS IN LIVER. THE PATIENT WAS STARTED ON ANTIBIOTICS FOR SEPSIS. AN ERCP WITH SPHINCTEROTOMY, BALLOON EXTRACTION, BALLOON SWEEP, AND PD STENT PLACEMENT WAS PERFORMED.' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	12 Nov 2020 13:01:23
User opened query 'Per CDM: Per response "corrected", however there is no change reflecting in eCRF, kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:05:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 06:04:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'corrected' (Site from System).	Flo Abbott (b) (4)	06 Nov 2020 18:58:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 17:23:58

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:34:36
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	18 Nov 2020 16:59:14
User entered '1'	System	05 Nov 2020 17:23:58
User entered '0'	System	05 Nov 2020 17:23:41

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	30 Oct 2020 16:19:17

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of ABDOMINAL NERVE PAIN noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:12:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:45:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:45:50
Query 'Per DM CLR: Please confirm if this AE is a worsening of ABDOMINAL NERVE PAIN noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:55:48
Data point term sent to Coder	System	26 Jan 2021 13:53:38
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:53:27
User entered 'WORSENING OF ABDOMINAL NERVE PAIN (EPIGASTRIC ABDOMINAL PAIN)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:53:27
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ABDOMINAL NERVE PAIN noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:10:06

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 11:07:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 11:07:49
Data point term sent to Coder	System	14 Dec 2020 19:46:21
User entered 'epigastric abdominal pain'	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '24 Aug 2020'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '30 Sep 2020'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'None (NONE)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:56:59
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4)	26 Jan 2021 13:55:56
User entered '0' reason for change: Data Entry Error	Morgan Mathis (b) (4)	26 Jan 2021 13:55:40
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:10:29
User entered '1'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Morgan Mathis (b) (4)	26 Jan 2021 13:55:40
User entered '0'	(b) (4)	
	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20
	(b) (4)	

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	14 Dec 2020 19:46:20

US3082051

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 20:40:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 20:40:22
Data point term sent to Coder	System	28 Jan 2021 20:39:45
User entered 'worsening headache'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '26 Aug 2020'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 19:29:10
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	15 Feb 2021 14:34:52
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	15 Feb 2021 14:34:03
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:16:44
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
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)	15 Feb 2021 14:34:44
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	15 Feb 2021 14:34:44
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	15 Feb 2021 14:34:03
User entered '30 Sep 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:34:03
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: AE Grade = 2, as this condition is listed as ongoing in the Med History (MODERATE HEADACHE) and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 2. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 19:30:22
Query 'Per DM CLR: AE Grade = 2, as this condition is listed as ongoing in the Med History (MODERATE HEADACHE) and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 2. Please review and update the grade or provide clarification.' answered with 'updated med history' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	15 Feb 2021 14:38:19
User opened query 'Per DM CLR: AE Grade = 2, as this condition is listed as ongoing in the Med History (MODERATE HEADACHE) and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 2. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:16:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'No (N)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'None (NONE)'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'I'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '0'	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:34:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40
	(b) (4)	

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered empty.	Ayssa Valente (b) (4)	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '0'	System	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered 'I'	System	28 Jan 2021 20:39:40

US3082051

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:40
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:46:24

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 16:50:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 16:50:43
Data point term sent to Coder	System	18 Aug 2020 16:49:31
User entered 'Synthroid'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:49:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:49:38
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:49:38
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:48:30
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Hypothyroidism'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered '75'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User closed query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 02:20:38
Query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' answered with 'Change Unit to ug for microgram' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	03 Sep 2020 15:24:40
User entered 'ug (ug)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	03 Sep 2020 15:23:12
User opened query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 07:37:38
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:52:09
User entered 'ug (ug)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty; reason for change Data Entry Error	Alice Cipollini (b) (4)	03 Sep 2020 15:23:12
User entered 'MCG' reason for change: New Information	(b) (4) Alice Cipollini (b) (4)	18 Aug 2020 16:52:09
User entered empty.	(b) (4) Alice Cipollini (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'once daily (QD)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
DataPoint Un-verified.	Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
User entered 'UN Jan 2008' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:48:58
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		19 Aug 2020 09:46:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Ongoing' (Site from System).	Alice Cipollini (b) (4)	18 Aug 2020 17:57:47
User entered '01 Jan 2008' reason for change: Data Entry Error	(b) (4)	18 Aug 2020 16:49:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 16:48:30
User entered '01 Jan 2020'	Alice Cipollini (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
DataPoint Un-verified.	Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
DataPoint Un-verified.	Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
User entered '09 Jul 2020' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	18 Aug 2020 16:48:30

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:16:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:16:49
Data point term sent to Coder	System	18 Aug 2020 17:59:49
User entered 'Imitrex'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Moderate Headaches'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered '50'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'mg (mg)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'as needed (PRN)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
DataPoint Un-verified.	Morgan Mathis (b) (4)	23 Nov 2020 15:31:53
User entered 'UN Jun 2019' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 15:31:53
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:48:58
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 09:46:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Ongoing' (Site from System).	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 17:59:10
User entered '01 Jun 2020'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered '0'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered empty.	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:48:58
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	18 Aug 2020 17:59:10

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
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.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 23:59:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 23:59:55
Data point term sent to Coder	System	26 Jan 2021 13:56:39
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:56:29
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)	15 Dec 2020 15:55:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:55:04
Data point term sent to Coder	System	14 Dec 2020 18:57:18
Coding entries removed.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 18:56:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:53:38

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:34:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:34:52
Data point term sent to Coder	System	23 Nov 2020 15:34:24
User entered 'ASPIRIN'	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'No (N)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'EPIGASTRIC ABDOMINAL PAIN (AE #6)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Morgan Mathis (b) (4)	26 Jan 2021 13:56:29
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:02:18
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:10:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated AE source. waiting for doctor signature to updated EDC' (Site from DM).	Erin Harrelson (b) (4)	14 Dec 2020 19:05:46
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Erin Harrelson (b) (4)	14 Dec 2020 19:04:25
DataPoint Un-verified.	(b) (4)	
User entered 'EPIGASTRIC ABDOMINAL PAIN' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 18:56:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:25:58

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 16:25:43
User entered 'CHEST PAIN'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered '80'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'ug (ug)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered empty.	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'once (ONCE)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered empty.	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered empty.	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered '24 Aug 2020'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered '0'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'No (N)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered '24 Aug 2020'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	(b) (4) Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User entered 'No (N)'	Morgan Mathis (b) (4)	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	(b) (4) Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Nov 2020 15:33:58
DataPoint activated with code reason code Data required.	Morgan Mathis (b) (4)	23 Nov 2020 15:32:30
DataPoint inactivated with code reason code Data not required.	Morgan Mathis (b) (4)	02 Oct 2020 16:44:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 13:59:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 13:59:07
Data point term sent to Coder	System	26 Jan 2021 13:57:40
Coding entries removed.	Morgan Mathis (b) (4)	26 Jan 2021 13:56:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:20:38
Data point term sent to Coder	System	23 Oct 2020 18:19:58
User entered 'Acetaminophen'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Un-verified.	(b) (4)	
	Morgan Mathis (b) (4)	26 Jan 2021 13:56:57
User entered 'ABDOMINAL PAIN (AE #6)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:56:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'abdominal pain'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '325'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'three times daily (TID)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:07:29
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:02:02
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'End date added to correlate with AE' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:28
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:24:05
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)- (b) (4)	05 Mar 2021 16:07:29
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	26 Feb 2021 14:59:40
User entered '8 Sep 2020' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:59:40
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	26 Feb 2021 14:58:15
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
User entered '30 Sep 2020' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 14:58:15
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '3'	System	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:19:17

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: CIPROFLOXACIN HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:25:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:25:30
Data point term sent to Coder	System	23 Oct 2020 18:21:02
User entered 'Ciprofloxacin HCL'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Acute Pancreatitis'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '500'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:20:59

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DUCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:23:43
Data point term sent to Coder	System	23 Oct 2020 18:23:06
User entered 'Ducusate'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Constipation'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '100'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:22:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:32:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:32:36
Data point term sent to Coder	System	23 Oct 2020 18:31:19
User entered 'Xarelto' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
Data point term sent to Coder	System	23 Oct 2020 18:25:10
User entered 'Levofloxacin'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Stroke prevention' reason for change:	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
Data Entry Error		
User entered 'Acute Pancreatitis'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '10' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
User entered '750'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)' reason for change:	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
Data Entry Error		
User entered 'once (ONCE)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:30:48
User entered '15 Jan 2019' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:30:48
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:25:09
User entered '30 Sep 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:31:08
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:31:08
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:31:08
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:25:09
User entered '30 Sep 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:30:48
User entered empty.	System	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:30:48
User entered empty.	System	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:30:48
User entered empty.	System	23 Oct 2020 18:25:09

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
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)	23 Oct 2020 18:35:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:35:34
Data point term sent to Coder	System	23 Oct 2020 18:34:23
User entered 'Tamsulosin'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: For Con Meds # 8 and 12 - Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:15:00
Query 'Per DM CLR: For Con Meds # 8 and 12 - Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH HAS BEEN UPDATED' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 14:58:48
User opened query 'Per DM CLR: For Con Meds # 8 and 12 - Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:26:59
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Benign Prostatic Hypertrophy'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0.4'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '18 Jan 2019'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:33:43

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:38:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' answered with 'AE filed, awaiting PI signature and grading' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 14:07:27
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 07:51:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:26:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:26:40
Data point term sent to Coder	System	14 Dec 2020 19:05:27
Coding entries removed.	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:05:25
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:46:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:46:46
Data point term sent to Coder	System	23 Oct 2020 18:45:43
User entered 'Propranolol'	Flo Abbott (b) (4) (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:02:40
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:17:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Ae has been created waiting for PI to sign and enter into EDC.' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:06:08
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Updated ' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:05:38
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:05:25
User entered 'Epigastric abdominal pain/HEADACHE' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:05:25
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:27:39

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 16:27:24
	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Chest pain/Headache'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '20'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'three times daily (TID)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:37:39
DataPoint Un-verified.	Morgan Mathis (b) (4)	15 Feb 2021 14:37:19
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:37:19
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	15 Feb 2021 14:37:39
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:37:39
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	15 Feb 2021 14:37:19
DataPoint Un-verified.	Morgan Mathis (b) (4)	15 Feb 2021 14:37:19
User entered '30 Sep 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Feb 2021 14:37:19
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '3'	System	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:45:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 14:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 14:03:28
Data point term sent to Coder	System	23 Oct 2020 18:47:53
User entered 'Lovenox'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Prevention of emboli'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '40'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Subcutaneous (SUBCUTANEOUS)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User closed query 'Per CDM: Response noted; however please update medication end date with month and year or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:08:02
Query 'Per CDM: Response noted; however please update medication end date with month and year or else clarify. Thank you.' answered with 'Pt received med in hospital for emboli prevention. end date updated.' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	30 Oct 2020 13:04:26
User entered 'No (N)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	30 Oct 2020 13:04:02
User opened query 'Per CDM: Response noted; however please update medication end date with month and year or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:29:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 16:46:39
Query 'Data is required. Please complete.' answered with 'medication is not ongoing but stopped after patient discontinued' (Site from System).	Flo Abbott (b) (4)	23 Oct 2020 18:49:51
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:49:12
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:49:12
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:53:38
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Nov 2020 15:39:58
User entered '08 Sep 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 15:39:58
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Nov 2020 15:38:02
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 15:38:02
User entered '30 Sep 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 15:38:02
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '30 Aug 2020' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	30 Oct 2020 13:04:02
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	23 Oct 2020 18:49:12
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	23 Oct 2020 18:48:42
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:48:42
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:48:42
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	23 Oct 2020 18:47:40
User entered '30 Sep 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 18:47:40

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 12:18:10
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 Jan 2021 12:18:10
Data point term sent to Coder	System	26 Jan 2021 13:58:40
Coding entries removed.	Morgan Mathis (b) (4)	26 Jan 2021 13:57:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:38:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:38:25
Data point term sent to Coder	System	23 Oct 2020 18:51:59
User entered 'Hydromorphone'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Un-verified.	Morgan Mathis (b) (4)	26 Jan 2021 13:57:46
User entered 'ABDOMINAL PAIN (AE #6)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	26 Jan 2021 13:57:46
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Abdominal pain'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'l'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once (ONCE)'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Intravenous (INTRAVENOUS)'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 18:52:10
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 18:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:51:49
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 18:51:49

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:21:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:21:33
Data point term sent to Coder	System	23 Oct 2020 19:20:57
User entered 'Proscar'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Benign Prostatic Hypertrophy'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '5'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '19 Jan 2019'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 19:20:55

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 16:04:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 16:04:43
Data point term sent to Coder	System	18 Dec 2020 16:02:43
Coding entries removed.	Erin Harrelson (b) (4)	18 Dec 2020 16:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:24:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:24:39
Data point term sent to Coder	System	23 Oct 2020 19:22:58
User entered 'Gabapentin'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per CDM, DM CLR re-query: Please update both the Indication for this medication and the MH page to reflect the location of NERVE PAIN. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 05:20:59
Query 'Per CDM, DM CLR re-query: Please update both the Indication for this medication and the MH page to reflect the location of NERVE PAIN. Thank you. ' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	18 Dec 2020 16:02:03
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	18 Dec 2020 16:01:57
User entered 'nerve pain [abdominal]' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	18 Dec 2020 16:01:57
User closed query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 15:13:31
User opened query 'Per CDM, DM CLR re-query: Please update both the Indication for this medication and the MH page to reflect the location of NERVE PAIN. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 15:13:30
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:03:44
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH HAS BEEN UPDATED. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:04:25
Query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'MEDICAL HISTORY HAS BEEN UPDATED. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:04:12

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:28:54
User opened query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:28:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Nerve pain'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '300'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mg (mg)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'three times daily (TID)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Oral (ORAL)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '15 Jan 2019'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '3'	System	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 19:22:01

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:40:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:40:26
Data point term sent to Coder	System	23 Oct 2020 19:24:02
User entered 'Iohexol'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Contrast for procedure'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '100'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mL (mL)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once (ONCE)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Intravenous (INTRAVENOUS)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:23:41

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
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) (b) (4)	24 Oct 2020 03:41:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:41:27
Data point term sent to Coder	System	23 Oct 2020 19:25:03
User entered 'Iopamidol'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Contrast for a procedure'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '100'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'mL (mL)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once (ONCE)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Intravenous (INTRAVENOUS)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered empty.	System	23 Oct 2020 19:25:02

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 17:02:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 17:02:52
Data point term sent to Coder	System	14 Dec 2020 15:01:51
Coding entries removed.	Morgan Mathis (b) (4)	14 Dec 2020 15:01:29
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:56:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:56:30
Data point term sent to Coder	System	23 Oct 2020 19:28:08
User entered 'Meropenem'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:41:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per DM CLR: Please update the indication to reflect the location and/or type of BACTERIAL INFECTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:04:16
User closed query 'Per DM CLR: This Conmed is given for the AE#5. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:04:05
Query 'Per DM CLR: Please update the indication to reflect the location and/or type of BACTERIAL INFECTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'BACTERIAL INFECTION IN THE BLOOD STREAM' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:01:54
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:01:29
User entered 'BACTERIAL INFECTION (SEPSIS)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 15:01:29
Query 'Per DM CLR: This Conmed is given for the AE#5. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'UPDATED. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 14:59:39
User opened query 'Per DM CLR: This Conmed is given for the AE#5. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:30:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and/or type of BACTERIAL INFECTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 16:30:05
	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Bacterial infection'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'l'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'g (g)'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:46
DataPoint Un-verified.	Ayssa Valente (b) (4)	11 Nov 2020 15:46:25
User entered 'three times daily (TID)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	11 Nov 2020 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'other (OTHER)'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:46
User closed query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. three times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:15:08
Query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. three times daily). Kindly update as appropriate, else clarify.' answered with 'frequency updated to option from list' (Site from DM).	Ayssa Valente (b) (4)	11 Nov 2020 15:46:30
DataPoint Un-verified.	Ayssa Valente (b) (4)	11 Nov 2020 15:46:25
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4)	11 Nov 2020 15:46:25
User opened query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. three times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:59:55
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'q8hr'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Intravenous (INTRAVENOUS)'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:34:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 19:34:50
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4)	23 Oct 2020 19:34:50
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:27:53
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '3'	System	11 Nov 2020 15:46:25
User entered empty.	System	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	11 Nov 2020 15:46:25
User entered empty.	System	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	11 Nov 2020 15:46:25
User entered empty.	System	23 Oct 2020 19:27:53

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:38:40
Data point term sent to Coder	System	23 Oct 2020 19:37:22
User entered 'Nicotine patch'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Smoking Cessation'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'l'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Other (OTHER)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Transdermal patch'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'once daily (QD)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Transdermal (TRANSDERMAL)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '26 Aug 2020'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered '0'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'Yes (Y)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered empty.	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:39:46
User entered 'No (N)'	Flo Abbott (b) (4)	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '1'	System	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User entered '804 (804)'	System	23 Oct 2020 19:36:21

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:03:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:41:39
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:32:38

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:41:56
User entered '28 Aug 2020'	Morgan Mathis (b) (4)	02 Oct 2020 12:35:56

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:41:56
User entered 'Endoscopic retrograde cholangiopancreatography with sphincterotomy, balloon extraction, balloon sweep, and PD stent placement.'	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:35:56

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:41:56
User entered 'Adverse Event (AE)'	Morgan Mathis (b) (4)	02 Oct 2020 12:35:56

US3082051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:41:56
User entered empty.	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:35:56

US3082051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:06

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:43:41
User entered '8 Sep 2020'	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:54:37

US3082051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:06

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:43:41
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	02 Oct 2020 12:31:29
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:54:37

US3082051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:16:30
User entered 'SAE#1' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 13:23:57
Query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 13:22:09
User entered 'Record line number 1' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 13:22:02
User opened query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:38:16
User closed query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 22:47:19
Query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field. Thank you. ' answered with 'Updated AE's. ' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	20 Nov 2020 16:05:55
Query ' Per CDM (re-query): Response noted, however data is not updated. Kindly consider to enter the record number instead of details.' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:04:46

US3082051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:03:29
User opened query ' Per CDM (re-query): Response noted, however data is not updated. Kindly consider to enter the record number instead of details.' (Site from DM).		19 Nov 2020 06:37:13
User closed query 'Per CDM: per CCGs please provide the record number instead of details.' (Site from DM).		19 Nov 2020 06:37:13
Query 'Per CDM: per CCGs please provide the record number instead of details.' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4)	18 Nov 2020 14:43:29
DataPoint Un-verified.	Morgan Mathis (b) (4)	18 Nov 2020 14:43:23
User entered	Morgan Mathis (b) (4)	18 Nov 2020 14:43:23
'USA-US114-2020-MRNA-1273-P301000002'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 11:25:54
User opened query 'Per CDM: per CCGs please provide the record number instead of details.' (Site from DM).		03 Nov 2020 13:43:41
DataPoint Verified.		
User entered 'Physician became aware of significant medical history after subject reported SAE and medical records were requested. Physical discontinued due to severity of previous diagnoses.'	Megan Marles (b) (4)	14 Sep 2020 15:54:37

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:44:03
User entered '8 Sep 2020'	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:55:40

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:44:03
User closed query 'Per CDM: Dosing Discontinuation, Primary reason for dosing discontinuation = SAE (specify); Study Discontinuation = Reason for discontinuation = Physician decision (specify). Please note that there are SAEs reported with Action taken = Investigational Product Withdrawn. Please update this field accordingly. ' (Site from DM).		30 Oct 2020 06:13:06
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	28 Oct 2020 19:09:03
User entered 'Physician decision (specify) (PHYSICIAN DECISION)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	28 Oct 2020 19:02:44
Query 'Per CDM: Dosing Discontinuation, Primary reason for dosing discontinuation = SAE (specify); Study Discontinuation = Reason for discontinuation = Physician decision (specify). Please note that there are SAEs reported with Action taken = Investigational Product Withdrawn. Please update this field accordingly. ' answered with 'HAS BEEN UPDATED TO SAE' (Site from DM).	Morgan Mathis (b) (4)	28 Oct 2020 19:02:28
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	28 Oct 2020 19:01:14
User opened query 'Per CDM: Dosing Discontinuation, Primary reason for dosing discontinuation = SAE (specify); Study Discontinuation = Reason for discontinuation = Physician decision (specify). Please note that there are SAEs reported with Action taken = Investigational Product Withdrawn. Please update this field accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:26:51
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Megan Marles (b) (4)	14 Sep 2020 15:55:40

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User closed query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:16:35
Query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 13:23:43
User entered 'SAE #1' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Nov 2020 13:23:38
User opened query 'Per CDM Re-query: update is noted; however please record record line number instead of AEID (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:38:32
User closed query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 22:47:14
Query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field on this page. Thank you.' answered with 'U[dated AE's' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	20 Nov 2020 16:06:37
Query 'Per CDM (re-query): Response noted, however data is not updated. Kindly consider to enter the record number instead of details.' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:05:28

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that there are several items with Action taken = Investigational Product Withdrawn. Please update the AE page as appropriate to have only one item recorded as study drug withdrawn and provide log line number of the AE/SAE in the Other, specify field on this page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:05:19
User opened query 'Per CDM (re-query): Response noted, however data is not updated. Kindly consider to enter the record number instead of details. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:36:55
User closed query 'Per CDM: per CCGs please provide the record number instead of details.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:36:55
Query 'Per CDM: per CCGs please provide the record number instead of details.' answered with 'updated.' (Site from DM).	Morgan Mathis (b) (4)	18 Nov 2020 14:43:56
DataPoint Un-verified.	(b) (4)	
	Morgan Mathis (b) (4)	18 Nov 2020 14:43:49
User entered 'USA-US114-2020-MRNA-1273-P301000002'	(b) (4)	
reason for change: Data Entry Error	Morgan Mathis (b) (4)	18 Nov 2020 14:43:49
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 11:25:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:44:03
User entered 'Discontinued by physician due to severity of previous medical conditions. Subject did not report medical history and site became aware of previous diagnoses after medical records were received.'	Megan Marles (b) (4)	14 Sep 2020 15:55:40
	(b) (4)	

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:44:03
Un-reviewed for Data Management.		22 Sep 2020 14:22:30
Reviewed for Data Management.		22 Sep 2020 14:22:25
User entered empty.	Megan Marles (b) (4)	14 Sep 2020 15:55:40
	(b) (4)	

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:44:03
User entered empty.	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:55:40

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:44:03
User entered empty.	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:55:40

US3082051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:06

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:44:03
User entered empty.	Megan Marles (b) (4) (b) (4)	14 Sep 2020 15:55:40

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
User entered '09/Sep/2020 10:04'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.		12 Sep 2020 17:25:05
User entered 'I'		09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
User entered '12/Sep/2020 13:25'	System	12 Sep 2020 17:25:15

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.		16 Sep 2020 19:28:42
User entered 'I'		12 Sep 2020 17:25:15

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
User entered '16/Sep/2020 15:28'	System	16 Sep 2020 19:28:58

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 13:05:48
DataPoint Verified.		23 Sep 2020 17:41:09
User entered 'I'		16 Sep 2020 19:28:58

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
User entered '02/Oct/2020 13:05'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.		16 Oct 2020 12:58:34
User entered 'I'		02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	System	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
User entered '16/Oct/2020 12:58'	System	16 Oct 2020 12:58:47

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:24:08
DataPoint Verified.		22 Oct 2020 13:01:12
User entered 'I'		16 Oct 2020 12:58:47

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	System	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:45:21
User entered '26/Oct/2020 20:24'	System	26 Oct 2020 20:24:28

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 17:30:40
DataPoint Verified.		03 Nov 2020 13:45:23
User entered 'I'		26 Oct 2020 20:24:28

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:26
User entered '06/Nov/2020 12:30'	System	06 Nov 2020 17:31:00

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:26
Reviewed for Safety.		09 Nov 2020 16:24:43
User entered 'I'		06 Nov 2020 17:31:00

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:26
User entered '09/Nov/2020 11:24'	System	09 Nov 2020 16:25:06

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:26
Reviewed for Safety.		13 Nov 2020 17:28:19
User entered 'I'		09 Nov 2020 16:25:06

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:26
User entered '13/Nov/2020 17:28'	System	13 Nov 2020 17:28:37

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 21:20:39
DataPoint Verified.		17 Nov 2020 18:02:26
User entered 'I'		13 Nov 2020 17:28:37

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:52:52
User entered '19/Nov/2020 21:21'	System	19 Nov 2020 21:21:32

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:10:56
DataPoint Verified.		24 Nov 2020 15:52:52
User entered 'I'		19 Nov 2020 21:21:32

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'USA-US114-2020-MRNA-1273-P301000002'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'Yes (Y)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 14:03:52
User entered 'No (N)'	System	09 Sep 2020 14:03:23

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Barton'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Williams'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '3806 Peachtree Ave.'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'Wilmington'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered 'NC'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:01:12
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:58:34
User entered '28403'	System	02 Oct 2020 13:06:01

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:17:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:25:05
User entered 'US' (non-conformant).	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '11'	(b) (4)	08 Dec 2020 15:11:11
User entered '10'	System	19 Nov 2020 21:21:32
User entered '9'	System	13 Nov 2020 17:28:37
User entered '8'	System	09 Nov 2020 16:25:06
User entered '7'	System	06 Nov 2020 17:31:00
User entered '6'	System	26 Oct 2020 20:24:28
User entered '5'	System	16 Oct 2020 12:58:47
User entered '4'	System	02 Oct 2020 13:06:01
User entered '3'	System	16 Sep 2020 19:28:58
User entered '2'	System	12 Sep 2020 17:25:15
User entered '1'	System	09 Sep 2020 14:04:16

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:03:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:40:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered '08/Dec/2020 10:11'	(b) (4) System	08 Dec 2020 15:11:11

US3082051

Folder: SAE USA-US114-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:03:06

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 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:40:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 16:52:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:11:11