

US3912024 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:19:45

All time stamps listed in this document are displayed in GMT

US3912024

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:01:16

Generated On: 10 Jun 2021 10:19:45

[Participant ID](#)

US3912024

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

US3912024

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	28 AUG 2020

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

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:01:20

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Date of Informed Consent (dd MMM yyyy)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:01:20

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:01:20

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	SEASONAL ALLERGIES (NASAL DRAINAGE, COUGH)
Start date (dd MMM yyyy)	UN UNK 1971
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1971
Start Year (derived)	1971
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	CHRON'S DISEASE
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	PARTIAL COLECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Condition	SHORT BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:30 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:30
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	140 lb
BMI (<i>xxx.x</i>)	20.12991 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:01:20

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:01:20

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188875

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:24
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	44 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 13:47 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 13:47

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

12:31 (24 HR)

Collection date and time (derived)

28 AUG 2020 12:31

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:41	28 AUG 2020 12:41
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

28 AUG 2020 14:37

PC Open Date & Time

28 AUG 2020 14:07

PC Close Date & Time

28 AUG 2020 16:37

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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 97.0 °F

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

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

PC Time Stamp	28 AUG 2020 19:25
PC Open Date & Time	28 AUG 2020 17:32
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

29 AUG 2020 20:13

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:36

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

31 AUG 2020 19:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

100.2 °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

01 SEP 2020 19:40

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 SEP 2020 19:47

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

98.2 °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

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 14:38

PC Open Date & Time

28 AUG 2020 14:07

PC Close Date & Time

28 AUG 2020 16:37

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

28 AUG 2020 19:26

PC Open Date & Time

28 AUG 2020 17:32

PC Close Date & Time

29 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

29 AUG 2020 20:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

30 AUG 2020 19:37

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

31 AUG 2020 19:43

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

01 SEP 2020 19:41

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:48

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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 ☐

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:39
PC Open Date & Time	28 AUG 2020 14:07
PC Close Date & Time	28 AUG 2020 16:37

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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 ☐

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 19:27
PC Open Date & Time	28 AUG 2020 17:32
PC Close Date & Time	29 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	29 AUG 2020 20:14
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	30 AUG 2020 19:37
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	31 AUG 2020 19:43
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	01 SEP 2020 19:42
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	02 SEP 2020 19:48
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

58 of 3501

EAB) (1725)

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	03 SEP 2020 20:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

04 SEP 2020 20:26

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 SEP 2020 20:26
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3912024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	24 SEP 2020

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

Folder OID	VISIT2

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:43
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	53 mmHg
Diastolic Blood Pressure units	MMHG

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 13:17
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3912024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 12:40 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 12:40

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

US3912024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	12:14 (24 HR)
Collection date and time (derived)	24 SEP 2020 12:14

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:19	24 SEP 2020 12:19
Nasopharyngeal Swab 2	No		

US3912024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

24 SEP 2020 13:22

PC Open Date & Time

24 SEP 2020 13:00

PC Close Date & Time

24 SEP 2020 15:30

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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 98.0 °F

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

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

PC Time Stamp	24 SEP 2020 20:32
PC Open Date & Time	24 SEP 2020 16:25
PC Close Date & Time	25 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

25 SEP 2020 20:55

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:28

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 22:34

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

29 SEP 2020 23:51

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

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

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:23

PC Open Date & Time

24 SEP 2020 13:00

PC Close Date & Time

24 SEP 2020 15:30

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

24 SEP 2020 20:33

PC Open Date & Time

24 SEP 2020 16:25

PC Close Date & Time

25 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

1

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

25 SEP 2020 20:56

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

26 SEP 2020 20:29

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

27 SEP 2020 20:22

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 22:35

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 23:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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 ☐

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

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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 ☐

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 13:23
PC Open Date & Time	24 SEP 2020 13:00
PC Close Date & Time	24 SEP 2020 15:30

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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 ☐

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 20:33
PC Open Date & Time	24 SEP 2020 16:25
PC Close Date & Time	25 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	25 SEP 2020 20:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	26 SEP 2020 20:30
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	27 SEP 2020 20:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	28 SEP 2020 22:35
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

EAB) (1725)

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US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

Yes ☐	
PC Time stamp	29 SEP 2020 23:53
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

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
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3912024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912024

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:01:20

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:01:35

Generated On: 10 Jun 2021 10:19:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:01:35

Generated On: 10 Jun 2021 10:19:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 10:41
Temperature (xxx.x)	36.2 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3912024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:01:21

Generated On: 10 Jun 2021 10:19:45

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	22 OCT 2020

Collection time (00:00-23:59)	12:27 (24 HR)

Collection date and time (derived)	22 OCT 2020 12:27

US3912024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 11:33:33

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3912024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:19:45

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

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Date of Contact	22 OCT 2020
Time of Contact	11:25
Date and Time of Contact (derived)	22 OCT 2020 11:25
Type of Contact	Clinic Visit - Scheduled ☒ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒ No ☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	17 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	18 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	19 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	20 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	21 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	22 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	24 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	25 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	26 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	27 OCT 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	36.8 C

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	28 OCT 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.5 F

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	29 OCT 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.1 F

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Date of Visit 27 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 27 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3912024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 11:10
Height (xxx.x)	70 in
Weight (xxx.x)	134.0 lb
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3912024

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

US3912024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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 _____

US3912024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3912024

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

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.

US3912024

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:45

Was Blood Sample Taken for Immunologic Assessment of	Yes ☐
SARS_COV-2 Infection?	No ☐
	NA (COVID-19 Negative) ☐

Date of Collection	

US3912024

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:01:16

Generated On: 10 Jun 2021 10:19:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID

Adverse event

FAINT RHONCHI LOWER LOBES

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)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	
Adverse event	COUGH
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)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID

Adverse event VOMITING

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) 17 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	FLANK PAIN (LEFT)
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

SUBJECT WENT TO ER ON 03NOV2020 FOR FLANK PAIN. SUBJECT DIAGNOSED WITH A LEFT RENAL STONE THAT REQUIRED RENAL STENT PLACEMENT. THE SUBJECT WAS INITIALLY ASSESSED ON 31OCT2020 WITH URETERAL STONES AND WAS DISCHARGED WITH RECOMMENDATION TO FOLLOW UP WITH PCP. SUBJECT DID NOT HAVE FOLLOW UP BUT ABDOMINAL PAIN HAD WORSENERED AND HE RETURNED TO THE ER. A CT OF ABDOMEN/PELVIS WAS PERFORMED ON 03NOV REVEALING OBSTRUCTING PROXIMAL LEFT URETERAL STONES MEASURING UP TO 9MM. OTHER FINDINGS INCLUDE MILD HYDRONEPHROSIS, AND INCREASED LEFT RENAL EDEMA; FINDINGS CONCERNING FOR PYELONEPHRITIS. UROLOGY WAS CONSULTED AND SUBJECT WAS TAKEN TO THE OR FOR URETERAL STENT PLACEMENT.

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

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	PERFORATED DUODENAL ULCER
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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☒ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ANEMIA
Narrative	

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

SUBJECT HOSPITALIZED FOR
COMPLICATIONS RELATED TO
RENAL STONE. CHARGE NURSE
AT HOSPITAL REPORTED
BOWEL PERFORATION VIA
PHONE CONVERSATION WITH
CRC, PENDING MEDICAL
RECORDS TO OBTAIN DATE
AND CAUSE OF PERFORATION.

UPDATE - AFTER FURTHER
REVIEW OF MEDICAL RECORDS
CHANGED TITLE OF ADVERSE
EVENT TO PERFORATED
DUODENAL ULCER.
ON 05NOV POST-OP DAY 1, THE
SUBJECT REPORTS ONGOING
ABDOMINAL PAIN; LATER
SAME DAY PLATELETS DROP
TO 59K, TRENDING DOWN
79K-73K-59K. WHILE THERE IS
NO REPORTED SIGNS OF
ACTIVE BLEEDING; SUBJECT
HAS ANOTHER CT OF
ABD/PELVIS ON 08NOV.
RESULTS REVEAL INCREASED
ATELECTASIS-CONSOLIDATION
BOTH LOWER LOBES WITH
NEW PATCHY INFILTRATE IN
POSTERIOR RIGHT UPPER
LOBE. MODERATELY LARGE
VOLUME OF
INTRAABDOMINAL FREE FLUID
W/LARGE AMOUNT OF
PNEUMOPERITONEUM NOTED.

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

PERFORATION IS SUSPECTED
BUT SITE COULD NOT BE
IDENTIFIED BY CT. SUBJECT
WAS TAKEN TO THE OR ON
08NOV, EXPLORATORY
LAPAROTOMY WAS
PERFORMED WITH CLOSURE
OF DUODENAL ULCER WITH
GRAHAM PATCH, EXTENSIVE
LYSIS OF DHESIONS, AND
DRAINAGE OF PERITONEAL
ABSCESSSES. A DRAIN WAS
BROUGHT OUT THROUGH
INCISION IN RIGHT UPPER
QUADRANT AND THEN PLACED
POSTERIOR SUPERIOR TO THE
ACTUAL ULCER. FOLLOW UP
CT WAS PERFORMED TO
ASSURE NO LEAK OR
OBSTRUCTION. HOWEVER, ON
13NOV CONTINUED TO HAVE
LEAKING OF DARK BROWN
FLUID FROM RIGHT SIDE
JP-SUBJECT UNDERGOES CT OF
ABD/ PELVIS WITH FOLLOWING
FINDINGS: INTERVAL
PLACEMENT OF A SURGICAL
DRAIN IN SUBHEPATIC SPACE
WITH DIMINISHING VOLUME
OF ASCITES. RESIDEUAL
GRAVITY DEPENDENT FLUID IS
NOTED IN PELVIS.
POSTSURGICAL CHANGE IN
THE VENTRAL ABDOMINAL
WALL, EDEMATOUS CHANGES

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

IN THE OMENTUM. THERE ARE
SMALL LOCULATIONS OF
FLUID ADJACENT TO THE
DESCENDING COLON;
WORSENING BIBASAL
PULMONARY INFILTRATES
AND PLEURAL EFFUSIONS;
WORSENING SOFT TISSUE
ANASARCA.

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

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	MULTISYSTEM ORGAN FAILURE
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	22 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
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Form: Adverse Events (7)

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Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☒ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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SITE WAS INFORMED THAT
SUBJECT PASSED AWAY BY
FAMILY MEMBER. RECORDS
REQUESTED. OBTAINED
MINIMAL NEW INFORMATION
AND ARE STILL PENDING
DEATH SUMMARY. VERY
LITTLE DETAIL KNOWN AT
THIS POINT HOWEVER, WILL
PROVIDE UPDATES AS
RECEIVED.

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

US3912024

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	ACUTE RENAL FAILURE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3912024

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

SUBJECT IN ACUTE RENAL FAILURE UPON HOSPITAL ADMISSION. 03NOV THRU 05NOV, CR 3.5, 3.1 AND 3.3 RESPECTIVELY. AN ULTRASOUND PERFORMED 06NOV TO FOLLOW UP ON HYDRONEPHROSIS REVEALED NO EVIDENCE OF HYDRONEPHROSIS. ON 18NOV SUBJECT HAD CHEST X-RAY (1 VIEW);CLINICAL INDICATION NOTED WAS RENAL FAILURE, FLUID OVERLOAD. FINDINGS WERE DEVELOPMENT OF DIFFUSE BILATERAL INTERSTITIAL INFILTRATES OR EDEMA, VOLUME LOSS THE LUNG BASES AND TRACE PLEURAL FLUID AT THE COSTOPHRENIC ANGLES. ON 19NOV CT OF ABD/PELVIS REVEALS THERE ARE DIFFUSE WATER DENSITY, SIMPLE APPEARING LOCULATED COLLECTIONS OF FLUID THROUGHOUT THE PERITONEAL CAVITY, LARGEST OF WHICH EXTENDS FROM THE LEFT UPPER QUADRANT CAUDALLY INTO THE PELVIS; NO ASSOCIATED INFLAMMATORY CHANGES OR FREE AIR. 20NOV CR2.3.

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	OBSTRUCTING NEPHROLITHIASIS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	31 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HOSPITALIZED WITH ACUTE KIDNEY FAILURE SECONDARY TO OBSTRUCTING NEPHROLITHIASIS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	THROMBOCYTOPENIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ARRIVED AT HOSPITAL WITH LOW PLATELETS. PLATELETS WOULD IMPROVE WITH TRANSFUSIONS BUT ULTIMATELY SUBJECT NEVER RECOVERED AND BLED OUT.

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Folder: Adverse Events

Form: Adverse Events (10)

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	ANEMIA
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)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

ANEMIA NOTED IN MEDICAL
RECORDS. SUBJECT REMAINED
ANEMIC UNTIL DEATH.
HGB ON ADMISSION 12.6 &
STABLE. ON 08NOV HGB
DROPPED TO 10.9, WITH
POST-OP WAS 8.7 ON 09NOV. ON
15NOV HGB DROPPED TO 6.2;
PRBC WERE GIVEN; ON 17NOV
HGB 7.8 AND HCT 23.7 WITH
PLATELET COUNT OF 31K.

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	22 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
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Form: Adverse Events (12)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☒ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

SUBJECT WENT INTO ACUTE
HYPOXIC RESPIRATORY
FAILURE WHICH RESULTED IN
SUBJECT BEING INTUBATED
AND MOVED TO ICU. SUBJECTS
FAMILY THEN DECIDED TO
DISCONTINUE ANY LIFE
SAVING MEASURES. SUBJECT
WAS TAKEN OFF OF
VENTILATOR ON 22NOV2020

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID

Adverse event

BIBASAL INFILTRATES,
PLEURAL EFFUSIONS,
WORSENING

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)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	0

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID

Adverse event

ATELECTASIS BILATERAL
LOWER LOBES

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)

5 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID

Adverse event

MALNUTRITION

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)

20 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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AEID

Adverse event

KLEBSIELLA COMPLICATED
PYELONEPHRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

3 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	ANASARCA
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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

ON 08NOV2020 THE SUBJECT
UNDERWENT AN
EXPLORATORY LAPAROTOMY
FOR WHAT WAS SUSPECTED TO
BE A BOWEL PERFORATION;
HOWEVER, ONCE THE
PROCEDURE WAS UNDERWAY,
IT WAS NOT A BOWEL
PERFORATION BUT DUODENAL
ULCER, WHICH WAS FURTHER
COMPLICATED BY
SIGNIFICANT ADHESIONS AND
MULTIPLE LOCULATED FLUID
COLLECTIONS. A CT
PERFORMED ON 13NOV2020
INDICATED WORSENING SOFT
TISSUE ANASARCA. AS LATE
AS 19NOV2020 THE SUBJECT
AGAIN DEVELOPED
COLLECTION OF FLUID
THROUGHOUT THE
PERITONEAL CAVITY,
LARGEST OF WHICH
EXTENDED FROM THE LEFT
UPPER QUADRANT CAUDALLY
INTO THE PELVIS.

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

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	GI BLEED
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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	22 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AT THE SUBJECT'S INITIAL
PRESENTATION TO THE ER ON
03NOV2020, THERE WERE A
HOST OF MEDICAL ISSUES
THAT APPEARED TO CASCADE
ONCE OBSTRUCTING
NEPHROLITHIASIS WAS
ADDRESSED WITH URETERAL
STENT PLACEMENT. THE
SUBJECT'S CONDITION WAS
COMPLICATED BY
THROMBOCYTOPENIA, A
DECLINE IN HEMOGLOBIN
DESPITE SEVERAL
TREATMENTS WITH BLOOD
PRODUCTS. ALTHOUGH THE
RECORDS INDICATE THAT
MONITORING FOR ONGOING
BLEEDING WAS TO CONTINUE,
THE SUBJECT DOES NOT
APPEAR TO STABILIZE; ON
20NOV2020, IT WAS NOTED
THAT THERE IS BLOOD IN THE
URINE; LATER THAT SAME
DAY, THE SUBJECT CODED.
DURING RESCUE MEASURES, IT
WAS NOTED THAT THE
SUBJECT HAD ACTIVE
BLEEDING IN THE BACK OF HIS
MOUTH, AS WELL AS THE
PRESENCE OF DRIED BLOOD.
THROUGHOUT THE RECORDS
IT APPEARS THAT THERE MAY
HAVE BEEN A STRONG
SUSPICION FOR

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

POST-OP BLEEDING; EFFORTS
TO RECOVER FROM
DECREASING PLATELETS AND
DOWN-TRENDING
HEMOGLOBIN WERE
UNSUCCESSFUL. ON
20NOV2020, THE FOLLOWING
LAB RESULTS WERE NOTED:
RBC=1.98; HGB=6.0; HCT=19.9;
PLTS=49.

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)	

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

AEID	USA-US211-2020-MRNA-1273-P30 1000006
Adverse event	INTRAABDOMINAL FLUID
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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	22 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

POST SURGERY FOR URETERAL
STENT PLACEMENT, IT WAS
NOTED ON RENAL
ULTRASOUND DATED
06NOV2020 THAT THERE WAS
SMALL VOLUME ASCITES; IT IS
NOTED ON 08NOV2020 THAT
SUBJECT HAD WORSENING OF
LOWER ABDOMINAL PAIN,
MORE CONSTANT AND
SEVERE, WITH DECREASE
APPETITE AND NAUSEA. A CT
ON 08NOV2020 REVEALED
"MODERATELY LARGE
VOLUME OF
INTRAABDOMINAL FREE
FLUID, WITH LARGE AMOUNT
OF PNEUMOPERITONEUM."
THE SUBJECT WAS TAKEN TO
THE OR ON 08NOV2020 WHERE
HE UNDERWENT CLOSURE OF
PERFORATED DUODENAL
ULCER, EXTENSIVE LYSIS OF
ADHESIONS AND DRAINAGE OF
PERITONEAL ABSCESES. THE
PERITONEAL CAVITY TOTAL
FLUID THAT WAS REMOVED
WAS ABOUT 1400ML OF
PURULENT FLUID.
SUBSEQUENTLY A JP DRAIN
WAS PLACED IN THE RIGHT
UPPER QUADRANT PRIOR TO
LEAVING THE OR. ON
13NOV2020 CT PERFORMED OF
THE ABDOMEN/PELVIS

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Mar 2021 13:43:41

Generated On: 10 Jun 2021 10:19:45

REVEALED FINDINGS OF
RESIDUAL ASCITES IN THE
PELVIS AND SMALL
LOCULATIONS OF FLUID
ADJACENT TO THE
DESCENDING COLON.
ABDOMINAL PAIN CONTINUES
THROUGH 17NOV2020, WITH
"YELLOW LIQUID FROM
AROUND THE JP DRAIN SITE
THAT IS DRENCHING THE BED".
A CT WAS PERFORMED ON
19NOV2020 REVEALING
"DIFFUSE WATER DENSITY,
SIMPLE APPEARING
LOCULATED COLLECTION OF
FLUID THROUGHOUT THE
PERITONEAL CAVITY,
LARGEST OF WHICH EXTENDS
FROM THE LEFT UPPER
QUADRANT CAUDALLY INTO
THE PELVIS". ON 20NOV2020
SUBJECT UNDERWENT
CT-GUIDED DRAINAGE AS
OPPOSED TO DRAINING
THROUGH THE DRAIN.

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

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 30 Mar 2021 13:43:41

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AEID

Adverse event

BIBASAL INFILTRATES

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)

8 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Form: Adverse Events (21)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 18:25:37

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication VOLTAREN 1%

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication PRESERVISION

Prophylaxis Yes ☒
No ☐

Indication VISION LOSS

Dose per administration 1

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

If dose unit is Other, specify SOFT GEL

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication MUCUS RELIEF DM

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 400/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ALLERGY RELIEF -
LEVOCETIRIZINE
DIHYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication NEILMED NASAL MIST
(SALINE)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication INFLUZENA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTING
NEPHROLITHIASIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication KLEBSIELLA COMPLICATED
PYELONEPHRITIS

Dose per administration 4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication MULTI-SYSTEM ORGAN FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTING
NEPHROLITHIASIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication TO PREVENT CLOTTING

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 4 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication KLEBSIELLA COMPLICATED
PYELONEPHRITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication FLOMAX

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication RISA-BID PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication TO MAINTAIN GUT HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 8 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication VERSED

Prophylaxis Yes ☐

No ☒

Indication ANXIETY

Dose per administration 1

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☐

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☒

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☐

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication XOPENEX NEBULIZER

Prophylaxis Yes ☐
No ☒

Indication ATELECTASIS, BILATERAL
LOWER LOBES

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTING
NEPHROLITHIASIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ATROVERT NEBULIZER

Prophylaxis Yes ☐
No ☒

Indication ATELECTASIS, BILATERAL
LOWER LOBES

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication KLEBSIELLA COMPLICATED
PYELONEPHRITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication SENOKOT
(SENNA/DOCUSATE SODIUM
8.6/50 MG)

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTING
NEPHROLITHIASIS

Dose per administration 17.2/100

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA FOLLOWING
LAPAROTOMY FOR
OBSTRUCTING
NEPHROLITHIASIS

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐
No ☒

Indication PAIN ASSOCIATED WITH
PERFORATED DUODENAL
ULCER

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication PROTONIX

Prophylaxis Yes ☒
No ☐

Indication GI PROTECTION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 9 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication CROHN'S DISEASE

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 6 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ALBUMIN

Prophylaxis Yes ☐
No ☒

Indication PROTEIN REPLACEMENT DUE
TO CIRRHOSIS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☒
No ☐

Indication POST OP INFECTION
PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Prophylaxis

Yes ☐

No ☐

Indication

Dose per administration

Dose unit

mg ☐

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency

once daily ☐

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration

Oral ☐

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	☐
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication ADULT TPN FORMULA

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
MALNUTRITION

Dose per administration 720

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication LOPRESSOR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 16 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERNATREMIA /LOW
POTASSIUM, ONGOING ACUTE
RENAL FAILURE

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication POTASSIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication CORRECTIVE SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify MM

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication FLUID OVERLOAD DUE TO
ACUTE RENAL FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication SEDATION FOR MECHANICAL
VENTILATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication BACTROBAN

Prophylaxis Yes ☐
No ☒

Indication RESTORE MOISTURE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication LEVOPHED

Prophylaxis Yes ☐
No ☒

Indication CURRENTLY UNKNOWN

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication CURRENTLY UNKNOWN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication CITRATE OF MAGNESIA

Prophylaxis Yes ☐
No ☒

Indication CURRENTLY UNKNOWN

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 ☐

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US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 07 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

Name of Medication NULECIT

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 18 Mar 2021 18:25:37

Generated On: 10 Jun 2021 10:19:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 NOV 2020	INTUBATION	Adverse Event	
15 NOV 2020	PACKED RED BLOOD CELLS	Adverse Event	
21 NOV 2020	PACKED RED BLOOD CELLS	Adverse Event	
8 NOV 2020	PLATELET TRANSFUSION	Adverse Event	
17 NOV 2020	PLATELET TRANSFUSION	Adverse Event	
8 NOV 2020	GRAHAM PATCH	Adverse Event	
3 NOV 2020	URETERAL STENT	Adverse Event	
8 NOV 2020	DRAIN PLACEMENT POSTERIOR SUPERIOR TO THE PERFORATED DUODENAL ULCER	Adverse Event	
8 NOV 2020	LYSIS OF ADHESIONS FROM ABDOMINAL WALL	Adverse Event	
4 NOV 2020	CYSTOURETHROSCOPY WITH LEFT RETROGRADE URETEROPYELOGRAM	Adverse Event	
3 NOV 2020	CT OF ABDOMEN/PELVIS	Diagnostic	
3 NOV 2020	X-RAY CYSTOGRAM	Diagnostic	
6 NOV 2020	RENAL ULTRASOUND	Diagnostic	
8 NOV 2020	CT OF ABDOMEN/PELVIS WITHOUT CONTRAST	Diagnostic	
8 NOV 2020	EXPLORATORY LAPAROTOMY WITH CLOSURE OF DUODENAL ULCER	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Data signed: (b) (4) 19 Feb 2021 16:01:18

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 NOV 2020	X-RAY UPPER GI	Diagnostic	
13 NOV 2020	CT OF ABDOMEN/PELVIS WITHOUT CONTRAST	Diagnostic	
15 NOV 2020	X-RAY ABDOMEN /KIDNEYS, URETER, BLADDER	Diagnostic	
18 NOV 2020	X-RAY CHEST	Adverse Event	
19 NOV 2020	CT ABDOMEN/PELVIS WITHOUT CONTRAST	Diagnostic	
20 NOV 2020	CT GUIDED DRAIN PLACEMENT	Adverse Event	
20 NOV 2020	X-RAY CHEST	Diagnostic	

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Feb 2021 16:01:19

Generated On: 10 Jun 2021 10:19:45

Date of study discontinuation/completion (dd MMM yyyy) 22 NOV 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☒
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

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

If reason for discontinuation is Death, main cause of death

Adverse event	☒
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 22 NOV 2020

Was autopsy performed?

Yes	☐
No	☒
Unknown	☐

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	16/NOV/2020 18:39
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	27/NOV/2020 09:43
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	27/NOV/2020 22:39
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	30/NOV/2020 19:38
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	21/DEC/2020 15:20
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	22/DEC/2020 11:33
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	28/DEC/2020 16:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	28/DEC/2020 17:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	30/DEC/2020 15:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	04/JAN/2021 14:34
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	22/JAN/2021 07:18
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	26/JAN/2021 08:10
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	29/JAN/2021 15:50
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	29/JAN/2021 16:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	11/FEB/2021 12:39
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	23/FEB/2021 09:28
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (17)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	24/FEB/2021 10:29
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (18)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	09/MAR/2021 12:26
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

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (19)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	15/MAR/2021 09:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (20)

Data signed: (b) (4) 31 Mar 2021 17:48:51

Generated On: 10 Jun 2021 10:19:45

SAEID	USA-US211-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	20
Date of submission (Pre-filled from custom function)	30/MAR/2021 08:25
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

Audit

US3912024 (Prod: Synexus - Optimal Research - Austin)

US3912024

Form: Participant Creation

Generated On: 10 Jun 2021 10:19:45

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:43:58
User entered 'US3912024'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:30

US3912024

Form: Participant Creation

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:44:09
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:34

US3912024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:44:09
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:31

US3912024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:44:09
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:34

US3912024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'SCRN'	System	28 Aug 2020 18:01:34

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:32

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '72'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'YEARS'	System	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '72'	System	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered 'Male (M)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:45:15
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:06

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Aug 2020'	System	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2020'	System	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered 'Amendment 3 (3)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered 'No (N)'	Tina Rountree (b) (4)	28 Aug 2020 18:01:53

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:50:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:31

US3912024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:21
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:19:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:34
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:19:24

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:59
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:26:38
Data point term sent to Coder	System	29 Aug 2020 21:26:03
User entered 'Anxiety'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:47:59
User entered 'un UNK 2012'	Tina Rountree (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:47:59
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:47:59
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:59
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:47:59
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 2012'	System	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2012'	System	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:25:28

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:41:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 06:25:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 06:25:28
Data point term sent to Coder	System	15 Oct 2020 15:44:37
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	15 Oct 2020 15:44:15
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	15 Oct 2020 15:44:15
User entered 'SEASONAL ALLERGIES (nasal drainage, cough)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Oct 2020 15:44:15
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:26:38
Data point term sent to Coder	System	29 Aug 2020 21:26:02
User entered 'Seasonal Allergies'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:09
User entered 'un UNK 1971'	Tina Rountree (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:09
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 1971'	System	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1971'	System	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:25:57

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 14:51:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4)	20 Jan 2021 23:21:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Jan 2021 23:21:10
Data point term sent to Coder	System	20 Jan 2021 23:20:53
Coding entries removed.	Sandra Clancy (b) (4)	20 Jan 2021 23:20:18
User entered 'BENIGN PROSTATIC hyperplasia' reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\23.0.	Sandra Clancy (b) (4)	20 Jan 2021 23:20:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Jan 2021 22:59:09
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	Coder Import (b) (4)	20 Jan 2021 22:59:09
Coding entries removed.	System	20 Jan 2021 22:58:40
User entered 'benign prostate hypertrophy' reason for change: Data Entry Error	Sandra Clancy (b) (4)	20 Jan 2021 22:58:08
DataPoint Verified.	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Sandra Clancy (b) (4)	20 Jan 2021 22:58:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 17:48:17
	Coder Import (b) (4)	29 Aug 2020 21:27:38
	(b) (4)	
	Coder Import (b) (4)	29 Aug 2020 21:27:38
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Aug 2020 21:27:03
User entered 'Overactive Bladder'	Tina Rountree (b) (4)	29 Aug 2020 21:26:28
	(b) (4)	

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:17
User entered 'un UNK 2016'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:17
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:17
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:17
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:17
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 2016'	System	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2016'	System	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:26:28

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:27:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:27:38
Data point term sent to Coder	System	29 Aug 2020 21:27:04
User entered 'Arthritis'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:24
User entered 'un UNK 2012'	Tina Rountree (b) (4)	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:24
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:01

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:24
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:24
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:27:01

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:24
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:27:01

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 2012'	System	29 Aug 2020 21:27:01

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2012'	System	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:27:01

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:29
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Crohn's disease, LLT: Crohn's disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:29:38
Data point term sent to Coder	System	29 Aug 2020 21:28:04
User entered 'Chron's Disease'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:29
User entered 'un UNK 1985'	Tina Rountree (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:29
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:29
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:29
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:29
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 1985'	System	29 Aug 2020 21:27:27

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1985'	System	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:27:27

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy partial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:29:38
Data point term sent to Coder	System	29 Aug 2020 21:29:05
User entered 'Partial Colectomy'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:35
User entered 'un UNK 1985'	Tina Rountree (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:35
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:35
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:05:43
User closed query 'Per SCRN Worksheet Page 7 of 9, stop date for Partial Colectomy is UN UNK 1985. Please provide source or correct.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 18:58:23
Query 'Per SCRN Worksheet Page 7 of 9, stop date for Partial Colectomy is UN UNK 1985. Please provide source or correct.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 13:08:59
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 13:08:52
User entered 'UN UNK 1985' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:08:52
User opened query 'Per SCRN Worksheet Page 7 of 9, stop date for Partial Colectomy is UN UNK 1985. Please provide source or correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:49:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:35
User entered 'un Nov 1985'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:35
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 1985'	System	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1985'	System	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 1985'	System	17 Sep 2020 13:08:52
User entered 'Nov 1985'	System	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1985'	System	29 Aug 2020 21:28:37

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Malabsorption conditions, HLT: Malabsorption syndromes, PT: Short-bowel syndrome, LLT: Short-bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:29:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:29:49
Data point term sent to Coder	System	29 Aug 2020 21:31:07
User entered 'Short Bowel Syndrome'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:40
User entered 'un UNK 1998'	Tina Rountree (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:48:40
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:40
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:40
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:48:40
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'Jan 1998'	System	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1998'	System	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:30:18

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered '11:30'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 11:30'	System	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered '70' in	Tina Rountree (b) (4)	29 Aug 2020 21:31:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered '140' lb	Tina Rountree (b) (4)	29 Aug 2020 21:31:43
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20.12991'	System	29 Aug 2020 21:31:43
DataPoint set to visible.	System	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'kg/m2'	System	29 Aug 2020 21:31:43
DataPoint set to visible.	System	28 Aug 2020 18:01:58

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:36:23
User entered '36.7' C	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered empty; reason for change Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:36:23
User entered 'Oral (Oral)'	(b) (4) Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:36:23
User entered '54'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'bpm'	System	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:36:23
User entered '14'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'breaths/min'	System	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:36:23
User entered '132'	Tina Rountree (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:36:23
User entered '70'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	29 Aug 2020 21:31:43

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:50:10
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:33:16

US3912024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:50:10
User entered '28 Aug 2020'	Tina Rountree (b) (4)	29 Aug 2020 21:33:16

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

[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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

US3912024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:36:51
User closed query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).		07 Oct 2020 19:51:37
Query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' answered with 'corrected' (Site from CRA).	Timothy Vachris (b) (4)	03 Oct 2020 17:11:24
DataPoint Un-verified.	(b) (4)	
	Timothy Vachris (b) (4)	03 Oct 2020 17:11:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	03 Oct 2020 17:11:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:58:29
User opened query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).		29 Sep 2020 20:58:05
DataPoint Un-verified.		29 Sep 2020 20:57:20
DataPoint Verified.		29 Sep 2020 20:57:16
DataPoint Un-verified.	Amy Collins (b) (4)	18 Sep 2020 20:42:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Collins (b) (4)	18 Sep 2020 20:42:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:05:49
User closed query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).		17 Sep 2020 18:58:34
Query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' answered with 'corrected ' (Site from CRA).		17 Sep 2020 13:10:06
DataPoint Un-verified.		17 Sep 2020 13:09:56
User entered 'No (N)' reason for change: Data Entry Error		17 Sep 2020 13:09:56
DataPoint Verified.		16 Sep 2020 17:46:00

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
User opened query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:45:56
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:36:53
User closed query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).		07 Oct 2020 19:51:39
Query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' answered with 'corrected' (Site from CRA).	Timothy Vachris (b) (4)	03 Oct 2020 17:11:27
DataPoint Un-verified.	(b) (4)	
	Timothy Vachris (b) (4)	03 Oct 2020 17:11:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	03 Oct 2020 17:11:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:58:30
User opened query 'Per eCRF guidelines, this section is for Occupational Risk'. Please clarify, or remove data. ' (Site from CRA).		29 Sep 2020 20:58:16
DataPoint Un-verified.	Amy Collins (b) (4)	18 Sep 2020 20:42:51
	(b) (4)	
User entered 'AGE > 65' reason for change: Data Entry Error	Amy Collins (b) (4)	18 Sep 2020 20:42:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:05:49
DataPoint Un-verified.		17 Sep 2020 13:09:56
User entered empty; reason for change Data Entry Error		17 Sep 2020 13:09:56
DataPoint Verified.		16 Sep 2020 17:46:00
User entered 'Over 65'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '1'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:35:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:46:00
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:52:43
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Aug 2020 18:02:22

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:43
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 18:02:22

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:52:43
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	28 Aug 2020 18:02:22

US3912024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'VISIT1'	System	28 Aug 2020 18:02:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered '188875'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).		08 Sep 2020 05:11:54
Query 'PER CDM: Please complete this section of the form.' answered with 'data updated ' (Site from DM).		02 Sep 2020 00:31:51
User entered 'No (N)'		02 Sep 2020 00:31:36
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).		31 Aug 2020 08:55:55

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered 'No (N)'		02 Sep 2020 00:31:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered 'No (N)'		02 Sep 2020 00:31:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered 'No (N)'		02 Sep 2020 00:31:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:24
User entered 'No (N)'		02 Sep 2020 00:31:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:41:07
User entered 'No (N)'	Mia Rountree (b) (4)	23 Oct 2020 21:43:47
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:27:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:27:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:10
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:10
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4)	02 Sep 2020 12:35:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:35:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:35:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:57
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:35:00
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '28 Aug 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '11:30' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Form: Vital Signs - Dosing (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 11:30'	System	02 Sep 2020 12:35:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '36.7' C reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered 'Oral (Oral)' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered empty.	Tina Rountree (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '54' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'bpm'	System	02 Sep 2020 12:35:57
User entered empty.	System	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '14' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'breaths/min'	System	02 Sep 2020 12:35:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '132' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	02 Sep 2020 12:35:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:21
User entered '70' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:35:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	02 Sep 2020 12:35:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:47:10
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:38:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:38:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:38:57
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:35:00
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered '28 Aug 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered '14:24' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 14:24'	System	02 Sep 2020 12:38:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered '36.3' C reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 05:27:31
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI. Two repeats obtained. 1432- 44BPM 1442-49BPM' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 13:12:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:03:12
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 12:38:57
User entered '44' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:38:57
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'bpm'	System	02 Sep 2020 12:38:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered '15' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'breaths/min'	System	02 Sep 2020 12:38:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	17 Sep 2020 00:09:38
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 00:09:38
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:09:38
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:03:12
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 12:38:57
User entered '161' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	02 Sep 2020 12:38:57
User entered empty.	System	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:03:12
User entered '71' reason for change: Data Entry Error	Tina Rountree (b) (4)	02 Sep 2020 12:38:57
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	02 Sep 2020 12:35:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	02 Sep 2020 12:38:57
User entered empty.	System	02 Sep 2020 12:35:00

US3912024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:04:03
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:35:53

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:04:03
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:35:53

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered empty.	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered empty.	Tina Rountree (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered '13:47'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 13:47'	System	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:00:01
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4) (b) (4)	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		16 Sep 2020 18:00:01
User entered 'ONCE'	System	28 Aug 2020 19:22:07

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 19:22:07

US3912024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:54:31
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:37:07

US3912024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:54:31
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:37:07

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:54:31
User entered '12:31'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:37:07

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 12:31'	System	29 Aug 2020 21:37:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:47
User entered '28 Aug 2020'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:39:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4)	29 Aug 2020 21:39:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:47
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:39:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:47
User entered '12:41'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '28 Aug 2020 12:41'	System	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4)	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:53:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:39:46

US3912024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:04:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:39:53

US3912024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Aug 2020 21:39:53

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:36:53', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f1208c6a-a12c-4b3f-949c-d247f8bcb02f'	System	28 Aug 2020 19:37:27
User entered 'Yes (Y)'	System	28 Aug 2020 19:37:27

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:37:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f1208c6a-a12c-4b3f-949c-d247f8bcb02f'	System	28 Aug 2020 19:37:27
User entered '97.3'	System	28 Aug 2020 19:37:27

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:37:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f1208c6a-a12c-4b3f-949c-d247f8bcb02f'	System	28 Aug 2020 19:37:27
User entered 'No (N)'	System	28 Aug 2020 19:37:27

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:37:20', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f1208c6a-a12c-4b3f-949c-d247f8bcb02f'	System	28 Aug 2020 19:37:27
User entered '28 Aug 2020 14:37'	System	28 Aug 2020 19:37:27

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 14:07'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 16:37'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:24:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '36635216-02ed-4fa4-87bf-6dc842ce56b4'	System	29 Aug 2020 00:25:22
User entered 'Yes (Y)'	System	29 Aug 2020 00:25:22

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:02', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '36635216-02ed-4fa4-87bf-6dc842ce56b4'	System	29 Aug 2020 00:25:22
User entered '97.0'	System	29 Aug 2020 00:25:22

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '36635216-02ed-4fa4-87bf-6dc842ce56b4'	System	29 Aug 2020 00:25:22
User entered 'No (N)'	System	29 Aug 2020 00:25:22

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:19', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '36635216-02ed-4fa4-87bf-6dc842ce56b4'	System	29 Aug 2020 00:25:22
User entered '28 Aug 2020 19:25'	System	29 Aug 2020 00:25:22

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 2'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:12:47', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e9641f7e-5f88-484c-834d-3f1be460243f'	System	30 Aug 2020 01:13:20
User entered 'Yes (Y)'	System	30 Aug 2020 01:13:20

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e9641f7e-5f88-484c-834d-3f1be460243f'	System	30 Aug 2020 01:13:20
User entered '97.5'	System	30 Aug 2020 01:13:20

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:07', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e9641f7e-5f88-484c-834d-3f1be460243f'	System	30 Aug 2020 01:13:20
User entered 'No (N)'	System	30 Aug 2020 01:13:20

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:16', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e9641f7e-5f88-484c-834d-3f1be460243f'	System	30 Aug 2020 01:13:20
User entered '29 Aug 2020 20:13'	System	30 Aug 2020 01:13:20

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 3'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:35:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '12745d02-2e47-47b6-ac95-7ad5ef21c8cf'	System	31 Aug 2020 00:39:09
User entered 'Yes (Y)'	System	31 Aug 2020 00:39:09

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:09', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '12745d02-2e47-47b6-ac95-7ad5ef21c8cf' User entered '97.7'	System	31 Aug 2020 00:39:09
	System	31 Aug 2020 00:39:09

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:14', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '12745d02-2e47-47b6-ac95-7ad5ef21c8cf'	System	31 Aug 2020 00:39:09
User entered 'No (N)'	System	31 Aug 2020 00:39:09

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:24', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '12745d02-2e47-47b6-ac95-7ad5ef21c8cf'	System	31 Aug 2020 00:39:09
User entered '30 Aug 2020 19:36'	System	31 Aug 2020 00:39:09

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 4'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:41:47', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1f5fa61f-f67e-43dc-953e-fca722543c06'	System	01 Sep 2020 00:42:14
User entered 'Yes (Y)'	System	01 Sep 2020 00:42:14

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:41:53', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1f5fa61f-f67e-43dc-953e-fca722543c06'	System	01 Sep 2020 00:42:14
User entered '97.5'	System	01 Sep 2020 00:42:14

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1f5fa61f-f67e-43dc-953e-fca722543c06'	System	01 Sep 2020 00:42:14
User entered 'No (N)'	System	01 Sep 2020 00:42:14

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1f5fa61f-f67e-43dc-953e-fca722543c06'	System	01 Sep 2020 00:42:14
User entered '31 Aug 2020 19:42'	System	01 Sep 2020 00:42:14

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 5'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:39:58', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7290c132-98f5-47a4-b19f-e6ea484f51fb'	System	02 Sep 2020 00:40:26
User entered 'Yes (Y)'	System	02 Sep 2020 00:40:26

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:06', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7290c132-98f5-47a4-b19f-e6ea484f51fb' User entered '100.2'	System	02 Sep 2020 00:40:26
	System	02 Sep 2020 00:40:26

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:12', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7290c132-98f5-47a4-b19f-e6ea484f51fb'	System	02 Sep 2020 00:40:26
User entered 'No (N)'	System	02 Sep 2020 00:40:26

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:22', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7290c132-98f5-47a4-b19f-e6ea484f51fb'	System	02 Sep 2020 00:40:26
User entered '01 Sep 2020 19:40'	System	02 Sep 2020 00:40:26

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 6'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '38456aea-587e-46d0-9bc8-1bb657b5748a'	System	03 Sep 2020 00:47:45
User entered 'Yes (Y)'	System	03 Sep 2020 00:47:45

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '38456aea-587e-46d0-9bc8-1bb657b5748a'	System	03 Sep 2020 00:47:45
User entered '97.3'	System	03 Sep 2020 00:47:45

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '38456aea-587e-46d0-9bc8-1bb657b5748a'	System	03 Sep 2020 00:47:45
User entered 'No (N)'	System	03 Sep 2020 00:47:45

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:39', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '38456aea-587e-46d0-9bc8-1bb657b5748a'	System	03 Sep 2020 00:47:45
User entered '02 Sep 2020 19:47'	System	03 Sep 2020 00:47:45

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 7'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:43:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1242e108-4647-4f30-9c63-dc8fc159d1db'	System	04 Sep 2020 01:44:16
User entered 'Yes (Y)'	System	04 Sep 2020 01:44:16

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:43:58', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1242e108-4647-4f30-9c63-dc8fc159d1db'	System	04 Sep 2020 01:44:16
User entered '98.2'	System	04 Sep 2020 01:44:16

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:03', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1242e108-4647-4f30-9c63-dc8fc159d1db'	System	04 Sep 2020 01:44:16
User entered 'No (N)'	System	04 Sep 2020 01:44:16

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1242e108-4647-4f30-9c63-dc8fc159d1db'	System	04 Sep 2020 01:44:16
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 01:44:16

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:37:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '81b440fd-2369-4f70-972e-610e10b4e1a5'	System	28 Aug 2020 19:39:28
User entered 'None (1)'	System	28 Aug 2020 19:39:28

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:37:43', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '81b440fd-2369-4f70-972e-610e10b4e1a5'	System	28 Aug 2020 19:39:28
User entered 'No (N)'	System	28 Aug 2020 19:39:28

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:02', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '81b440fd-2369-4f70-972e-610e10b4e1a5'	System	28 Aug 2020 19:39:28
User entered 'No (N)'	System	28 Aug 2020 19:39:28

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:12', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '81b440fd-2369-4f70-972e-610e10b4e1a5'	System	28 Aug 2020 19:39:28
User entered 'None (1)'	System	28 Aug 2020 19:39:28

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '81b440fd-2369-4f70-972e-610e10b4e1a5'	System	28 Aug 2020 19:39:28
User entered '28 Aug 2020 14:38'	System	28 Aug 2020 19:39:28

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 14:07'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 16:37'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '608cea09-e8be-438b-a960-975779709833'	System	29 Aug 2020 00:26:21
User entered 'None (1)'	System	29 Aug 2020 00:26:21

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:41', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '608cea09-e8be-438b-a960-975779709833'	System	29 Aug 2020 00:26:21
User entered 'No (N)'	System	29 Aug 2020 00:26:21

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:25:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '608cea09-e8be-438b-a960-975779709833'	System	29 Aug 2020 00:26:21
User entered 'No (N)'	System	29 Aug 2020 00:26:21

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:10', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '608cea09-e8be-438b-a960-975779709833'	System	29 Aug 2020 00:26:21
User entered 'None (1)'	System	29 Aug 2020 00:26:21

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:19', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '608cea09-e8be-438b-a960-975779709833'	System	29 Aug 2020 00:26:21
User entered '28 Aug 2020 19:26'	System	29 Aug 2020 00:26:21

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 2'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '67301b90-8699-46eb-ab2c-54657dee279b'	System	30 Aug 2020 01:14:12
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 01:14:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '67301b90-8699-46eb-ab2c-54657dee279b'	System	30 Aug 2020 01:14:12
User entered 'No (N)'	System	30 Aug 2020 01:14:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:47', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '67301b90-8699-46eb-ab2c-54657dee279b'	System	30 Aug 2020 01:14:12
User entered 'No (N)'	System	30 Aug 2020 01:14:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:13:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '67301b90-8699-46eb-ab2c-54657dee279b'	System	30 Aug 2020 01:14:12
User entered 'None (1)'	System	30 Aug 2020 01:14:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:06', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '67301b90-8699-46eb-ab2c-54657dee279b'	System	30 Aug 2020 01:14:12
User entered '29 Aug 2020 20:14'	System	30 Aug 2020 01:14:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 3'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:46', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ad20e69c-3857-4f41-809f-42a0edc82f18'	System	31 Aug 2020 00:39:15
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 00:39:15

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ad20e69c-3857-4f41-809f-42a0edc82f18'	System	31 Aug 2020 00:39:15
User entered 'No (N)'	System	31 Aug 2020 00:39:15

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:54', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ad20e69c-3857-4f41-809f-42a0edc82f18'	System	31 Aug 2020 00:39:15
User entered 'No (N)'	System	31 Aug 2020 00:39:15

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:36:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ad20e69c-3857-4f41-809f-42a0edc82f18'	System	31 Aug 2020 00:39:15
User entered 'None (1)'	System	31 Aug 2020 00:39:15

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ad20e69c-3857-4f41-809f-42a0edc82f18'	System	31 Aug 2020 00:39:15
User entered '30 Aug 2020 19:37'	System	31 Aug 2020 00:39:15

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 4'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '86f7c633-f461-4ae1-bb1e-36a3f6fbda52'	System	01 Sep 2020 00:43:09
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 00:43:09

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:25', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '86f7c633-f461-4ae1-bb1e-36a3f6fbda52'	System	01 Sep 2020 00:43:09
User entered 'No (N)'	System	01 Sep 2020 00:43:09

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '86f7c633-f461-4ae1-bb1e-36a3f6fbda52'	System	01 Sep 2020 00:43:09
User entered 'No (N)'	System	01 Sep 2020 00:43:09

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:42:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '86f7c633-f461-4ae1-bb1e-36a3f6fbda52'	System	01 Sep 2020 00:43:09
User entered 'None (1)'	System	01 Sep 2020 00:43:09

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:06', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '86f7c633-f461-4ae1-bb1e-36a3f6fbda52'	System	01 Sep 2020 00:43:09
User entered '31 Aug 2020 19:43'	System	01 Sep 2020 00:43:09

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 5'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'bc819889-7022-4ce1-b435-ef7cab1be7b4'	System	02 Sep 2020 00:41:20
User entered 'None (1)'	System	02 Sep 2020 00:41:20

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'bc819889-7022-4ce1-b435-ef7cab1be7b4'	System	02 Sep 2020 00:41:20
User entered 'No (N)'	System	02 Sep 2020 00:41:20

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:51', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'bc819889-7022-4ce1-b435-ef7cab1be7b4'	System	02 Sep 2020 00:41:20
User entered 'No (N)'	System	02 Sep 2020 00:41:20

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:40:57', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'bc819889-7022-4ce1-b435-ef7cab1be7b4'	System	02 Sep 2020 00:41:20
User entered 'None (1)'	System	02 Sep 2020 00:41:20

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'bc819889-7022-4ce1-b435-ef7cab1be7b4'	System	02 Sep 2020 00:41:20
User entered '01 Sep 2020 19:41'	System	02 Sep 2020 00:41:20

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 6'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:46', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ac4ca271-66db-44ae-a382-072fc5df1146'	System	03 Sep 2020 00:48:12
User entered 'None (1)'	System	03 Sep 2020 00:48:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ac4ca271-66db-44ae-a382-072fc5df1146'	System	03 Sep 2020 00:48:12
User entered 'No (N)'	System	03 Sep 2020 00:48:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:47:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ac4ca271-66db-44ae-a382-072fc5df1146'	System	03 Sep 2020 00:48:12
User entered 'No (N)'	System	03 Sep 2020 00:48:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ac4ca271-66db-44ae-a382-072fc5df1146'	System	03 Sep 2020 00:48:12
User entered 'None (1)'	System	03 Sep 2020 00:48:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:09', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'ac4ca271-66db-44ae-a382-072fc5df1146'	System	03 Sep 2020 00:48:12
User entered '02 Sep 2020 19:48'	System	03 Sep 2020 00:48:12

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 7'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:20', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '388e541b-db27-41aa-9f7a-03316036dd30'	System	04 Sep 2020 01:44:43
User entered 'None (1)'	System	04 Sep 2020 01:44:43

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:24', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '388e541b-db27-41aa-9f7a-03316036dd30'	System	04 Sep 2020 01:44:43
User entered 'No (N)'	System	04 Sep 2020 01:44:43

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '388e541b-db27-41aa-9f7a-03316036dd30'	System	04 Sep 2020 01:44:43
User entered 'No (N)'	System	04 Sep 2020 01:44:43

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:32', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '388e541b-db27-41aa-9f7a-03316036dd30'	System	04 Sep 2020 01:44:43
User entered 'None (1)'	System	04 Sep 2020 01:44:43

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '388e541b-db27-41aa-9f7a-03316036dd30'	System	04 Sep 2020 01:44:43
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 01:44:43

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:32', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:41', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:45', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:38:53', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'None (0)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:39:13', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered 'No (N)'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T14:39:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '18997198-47db-4bcc-a937-5c9e31226f4b'	System	28 Aug 2020 19:39:33
User entered '28 Aug 2020 14:39'	System	28 Aug 2020 19:39:33

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 14:07'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 16:37'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:36', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:45', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'None (0)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:51', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'None (0)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:26:58', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'None (0)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:27:02', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'None (0)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:27:13', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'None (0)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:27:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered 'No (N)'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-28T19:27:49', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3bf40b46-1be9-4869-a5aa-31dc7be92068'	System	29 Aug 2020 00:27:53
User entered '28 Aug 2020 19:27'	System	29 Aug 2020 00:27:53

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 2'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:13', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:22', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:26', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:31', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:34', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:39', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'None (0)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:43', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered 'No (N)'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-29T20:14:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '2ff28f6d-de21-4e2f-a2c1-2c288358d491'	System	30 Aug 2020 01:14:58
User entered '29 Aug 2020 20:14'	System	30 Aug 2020 01:14:58

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 3'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:18', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:22', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:25', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:29', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:36', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'None (0)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered 'No (N)'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-30T19:37:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b66b33ef-a4d2-4a21-bc54-9ebf0427437d'	System	31 Aug 2020 00:39:29
User entered '30 Aug 2020 19:37'	System	31 Aug 2020 00:39:29

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 4'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:13', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:17', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:25', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:30', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'None (0)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:34', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered 'No (N)'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-08-31T19:43:44', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'cc10fe84-9ade-45cb-ae74-490fe5f69037'	System	01 Sep 2020 00:43:46
User entered '31 Aug 2020 19:43'	System	01 Sep 2020 00:43:46

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 5'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:19', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:32', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:44', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:41:54', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'None (0)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:42:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered 'No (N)'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-01T19:42:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'f2438b53-e1f7-4ab5-94f7-b511b633e3f4'	System	02 Sep 2020 00:42:38
User entered '01 Sep 2020 19:42'	System	02 Sep 2020 00:42:38

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 6'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:19', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:25', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:31', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:35', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:41', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'None (0)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:49', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered 'No (N)'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-02T19:48:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '05c1d77d-cf4f-4118-abf8-8eb5679e4f8d'	System	03 Sep 2020 00:49:01
User entered '02 Sep 2020 19:48'	System	03 Sep 2020 00:49:01

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 7'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:44:57', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'No interference with activity (1)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'None (0)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:07', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'None (0)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:10', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'None (0)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:14', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'None (0)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:17', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'None (0)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered 'No (N)'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-03T20:45:29', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '692bfcc8-b090-40c5-8711-dd47821bd22e'	System	04 Sep 2020 01:45:31
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	04 Sep 2020 01:45:31
User entered 'Day 8'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-04T20:26:24', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1ed091e0-ffe9-4375-84c1-dcdee0974920'	System	05 Sep 2020 01:26:32
User entered 'None (0)'	System	05 Sep 2020 01:26:32

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-04T20:26:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '1ed091e0-ffe9-4375-84c1-dcdee0974920'	System	05 Sep 2020 01:26:32
User entered '04 Sep 2020 20:26'	System	05 Sep 2020 01:26:32

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	04 Sep 2020 01:45:31
User entered 'Day 8'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-04T20:26:39', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '24ff4d4d-0e50-40d1-b583-e223c8caa260'	System	05 Sep 2020 01:26:49
User entered 'No (N)'	System	05 Sep 2020 01:26:49

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-04T20:26:46', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '24ff4d4d-0e50-40d1-b583-e223c8caa260'	System	05 Sep 2020 01:26:49
User entered '04 Sep 2020 20:26'	System	05 Sep 2020 01:26:49

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 01:45:31

US3912024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 01:45:31

US3912024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:06:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 01:14:17

US3912024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:06:10
User entered '04 Sep 2020'		05 Sep 2020 01:14:17

US3912024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:06:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Sep 2020 01:14:17

US3912024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:06:10
User entered empty.		05 Sep 2020 01:14:17

US3912024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:07:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 01:14:21

US3912024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	05 Sep 2020 01:14:21

US3912024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 21:35:48

US3912024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:11:19
User entered '11 Sep 2020'		11 Sep 2020 21:35:48

US3912024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:11:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 21:35:48

US3912024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:11:19
User entered empty.		11 Sep 2020 21:35:48

US3912024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:11:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 21:35:53

US3912024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	11 Sep 2020 21:35:53

US3912024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:56:47
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 20:43:23

US3912024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:56:47
User entered '18 Sep 2020'	Amy Collins (b) (4)	18 Sep 2020 20:43:23

US3912024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:56:47
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	18 Sep 2020 20:43:23

US3912024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:56:47
User entered empty.	Amy Collins (b) (4)	18 Sep 2020 20:43:23

US3912024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:56:56
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 20:43:29

US3912024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Sep 2020 20:43:29

US3912024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:59:56
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:05:33

US3912024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:59:56
User entered '24 Sep 2020'	Amy Collins (b) (4)	24 Sep 2020 17:05:33

US3912024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:59:56
User entered 'Clinic (Clinic)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:05:33

US3912024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'VISIT2'	System	24 Sep 2020 17:05:33

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User accepted default value 'Pre-Dose (PREDOSE)'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '24 Sep 2020'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '11:43'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '24 Sep 2020 11:43'	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '36.4' C	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered 'Oral (Oral)'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '61'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'bpm'	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '14'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'breaths/min'	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '105'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'PER CDM: Re-Query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:11:02
Query 'PER CDM: Re-Query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate. Thank you. ' answered with 'ncs' (Site from DM).	Timothy Vachris (b) (4)	05 Oct 2020 17:35:34
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:04:54
User opened query 'PER CDM: Re-Query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate. Thank you. ' (Site from DM).		28 Sep 2020 11:05:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Sep 2020 11:05:30
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'data correct' (Site from System).		26 Sep 2020 17:36:39
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Sep 2020 17:56:18
User entered '53'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User accepted default value 'Post-Dose (POSTDOSE)'	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 17:34:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 17:34:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 17:34:44
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 17:56:18
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '24 Sep 2020' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '13:17' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '24 Sep 2020 13:17'	System	26 Sep 2020 17:34:44
User entered empty.	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '97.2' F reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered 'Oral (Oral)' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '51' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'bpm'	System	26 Sep 2020 17:34:44
User entered empty.	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '18' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'breaths/min'	System	26 Sep 2020 17:34:44
User entered empty.	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '137' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	26 Sep 2020 17:34:44
User entered empty.	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:04:54
User entered '75' reason for change: Data Entry Error		26 Sep 2020 17:34:44
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	26 Sep 2020 17:34:44
User entered empty.	System	24 Sep 2020 17:56:18

US3912024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:06:58
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:05:44

US3912024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:06:58
User entered '24 Sep 2020'	Amy Collins (b) (4)	24 Sep 2020 17:05:44

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered empty.	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered '24 Sep 2020'	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered '12:40'	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '24 Sep 2020 12:40'	System	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:32
User entered 'Left Arm (LEFT ARM)'	Monique Gawlik (b) (4)	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
DataPoint Verified.		29 Sep 2020 21:08:32
User entered 'ONCE'	System	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 17:44:42

US3912024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:13
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:16

US3912024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:08:13
User entered '24 Sep 2020'	Amy Collins (b) (4)	24 Sep 2020 17:26:16

US3912024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:08:13
User entered '12:14'	Amy Collins (b) (4)	24 Sep 2020 17:26:16

US3912024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '24 Sep 2020 12:14'	System	24 Sep 2020 17:26:16

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:08:19
User entered '24 Sep 2020'	Amy Collins (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:19
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:08:19
User entered '12:19'	Amy Collins (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '24 Sep 2020 12:19'	System	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:19
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:19
User entered empty.	Amy Collins (b) (4) (b) (4)	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	24 Sep 2020 17:26:35

US3912024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:08:25
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	24 Sep 2020 17:57:10

US3912024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	24 Sep 2020 17:57:10

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:20', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '51280015-63ea-484e-ab5f-f38b8b49cdd0'	System	24 Sep 2020 18:24:16
User entered 'Yes (Y)'	System	24 Sep 2020 18:24:16

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '51280015-63ea-484e-ab5f-f38b8b49cdd0'	System	24 Sep 2020 18:24:16
User entered '97.2'	System	24 Sep 2020 18:24:16

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:34', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '51280015-63ea-484e-ab5f-f38b8b49cdd0'	System	24 Sep 2020 18:24:16
User entered 'No (N)'	System	24 Sep 2020 18:24:16

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:44', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '51280015-63ea-484e-ab5f-f38b8b49cdd0'	System	24 Sep 2020 18:24:16
User entered '24 Sep 2020 13:22'	System	24 Sep 2020 18:24:16

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 13:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 15:30'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:31:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7ab26e40-3e42-42b4-a387-0a7a3523235a'	System	25 Sep 2020 01:32:15
User entered 'Yes (Y)'	System	25 Sep 2020 01:32:15

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:31:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7ab26e40-3e42-42b4-a387-0a7a3523235a'	System	25 Sep 2020 01:32:15
User entered '98.0'	System	25 Sep 2020 01:32:15

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:03', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7ab26e40-3e42-42b4-a387-0a7a3523235a'	System	25 Sep 2020 01:32:15
User entered 'No (N)'	System	25 Sep 2020 01:32:15

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7ab26e40-3e42-42b4-a387-0a7a3523235a'	System	25 Sep 2020 01:32:15
User entered '24 Sep 2020 20:32'	System	25 Sep 2020 01:32:15

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 16:25'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 2'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:54:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '9455f848-fc13-4855-a74d-7b2e7d86eedf'	System	26 Sep 2020 01:55:10
User entered 'Yes (Y)'	System	26 Sep 2020 01:55:10

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:54:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '9455f848-fc13-4855-a74d-7b2e7d86eedf'	System	26 Sep 2020 01:55:10
User entered '98.1'	System	26 Sep 2020 01:55:10

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:55:00', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '9455f848-fc13-4855-a74d-7b2e7d86eedf'	System	26 Sep 2020 01:55:10
User entered 'No (N)'	System	26 Sep 2020 01:55:10

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:55:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '9455f848-fc13-4855-a74d-7b2e7d86eedf'	System	26 Sep 2020 01:55:10
User entered '25 Sep 2020 20:55'	System	26 Sep 2020 01:55:10

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 3'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:27:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7cac8c7a-a6c6-46c6-80c8-69b451f80059'	System	27 Sep 2020 01:28:19
User entered 'Yes (Y)'	System	27 Sep 2020 01:28:19

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:03', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7cac8c7a-a6c6-46c6-80c8-69b451f80059'	System	27 Sep 2020 01:28:19
User entered '99.1'	System	27 Sep 2020 01:28:19

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7cac8c7a-a6c6-46c6-80c8-69b451f80059'	System	27 Sep 2020 01:28:19
User entered 'No (N)'	System	27 Sep 2020 01:28:19

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:16', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '7cac8c7a-a6c6-46c6-80c8-69b451f80059'	System	27 Sep 2020 01:28:19
User entered '26 Sep 2020 20:28'	System	27 Sep 2020 01:28:19

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 4'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:21:31', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6a620552-120f-43f8-9e55-57e9d7730c9f'	System	28 Sep 2020 01:21:52
User entered 'Yes (Y)'	System	28 Sep 2020 01:21:52

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:21:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6a620552-120f-43f8-9e55-57e9d7730c9f' User entered '99.0'	System	28 Sep 2020 01:21:52
	System	28 Sep 2020 01:21:52

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:21:42', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6a620552-120f-43f8-9e55-57e9d7730c9f'	System	28 Sep 2020 01:21:52
User entered 'No (N)'	System	28 Sep 2020 01:21:52

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:21:49', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6a620552-120f-43f8-9e55-57e9d7730c9f'	System	28 Sep 2020 01:21:52
User entered '27 Sep 2020 20:21'	System	28 Sep 2020 01:21:52

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 5'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:34:32', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '92528e1a-ff5c-4c9a-8db5-afd96cd2afda'	System	29 Sep 2020 03:34:58
User entered 'Yes (Y)'	System	29 Sep 2020 03:34:58

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:34:38', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '92528e1a-ff5c-4c9a-8db5-afd96cd2afda'	System	29 Sep 2020 03:34:58
User entered '97.7'	System	29 Sep 2020 03:34:58

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:34:41', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '92528e1a-ff5c-4c9a-8db5-afd96cd2afda'	System	29 Sep 2020 03:34:58
User entered 'No (N)'	System	29 Sep 2020 03:34:58

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:34:54', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '92528e1a-ff5c-4c9a-8db5-afd96cd2afda'	System	29 Sep 2020 03:34:58
User entered '28 Sep 2020 22:34'	System	29 Sep 2020 03:34:58

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 6'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:50:48', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e7b13e0c-1996-4a8c-a2e6-fd18fc929da2'	System	30 Sep 2020 04:51:12
User entered 'Yes (Y)'	System	30 Sep 2020 04:51:12

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:00', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e7b13e0c-1996-4a8c-a2e6-fd18fc929da2'	System	30 Sep 2020 04:51:12
User entered '97.3'	System	30 Sep 2020 04:51:12

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:04', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e7b13e0c-1996-4a8c-a2e6-fd18fc929da2'	System	30 Sep 2020 04:51:12
User entered 'No (N)'	System	30 Sep 2020 04:51:12

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:10', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'e7b13e0c-1996-4a8c-a2e6-fd18fc929da2'	System	30 Sep 2020 04:51:12
User entered '29 Sep 2020 23:51'	System	30 Sep 2020 04:51:12

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 7'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:54', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3faaf253-14e5-4c03-9e40-0ce1992da23b'	System	24 Sep 2020 18:24:47
User entered 'None (1)'	System	24 Sep 2020 18:24:47

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:22:58', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3faaf253-14e5-4c03-9e40-0ce1992da23b'	System	24 Sep 2020 18:24:47
User entered 'No (N)'	System	24 Sep 2020 18:24:47

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3faaf253-14e5-4c03-9e40-0ce1992da23b'	System	24 Sep 2020 18:24:47
User entered 'No (N)'	System	24 Sep 2020 18:24:47

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:05', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3faaf253-14e5-4c03-9e40-0ce1992da23b'	System	24 Sep 2020 18:24:47
User entered 'None (1)'	System	24 Sep 2020 18:24:47

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3faaf253-14e5-4c03-9e40-0ce1992da23b'	System	24 Sep 2020 18:24:47
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 18:24:47

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 13:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 15:30'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:20', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'a09e99a0-8966-47a9-8830-2f269d483990'	System	25 Sep 2020 01:33:12
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 01:33:12

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:29', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'a09e99a0-8966-47a9-8830-2f269d483990'	System	25 Sep 2020 01:33:12
User entered 'No (N)'	System	25 Sep 2020 01:33:12

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:42', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'a09e99a0-8966-47a9-8830-2f269d483990'	System	25 Sep 2020 01:33:12
User entered 'No (N)'	System	25 Sep 2020 01:33:12

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:32:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'a09e99a0-8966-47a9-8830-2f269d483990'	System	25 Sep 2020 01:33:12
User entered 'None (1)'	System	25 Sep 2020 01:33:12

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'a09e99a0-8966-47a9-8830-2f269d483990'	System	25 Sep 2020 01:33:12
User entered '24 Sep 2020 20:33'	System	25 Sep 2020 01:33:12

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 16:25'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 2'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:55:17', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:55:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered 'No (N)'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:55:29', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered 'Yes (Y)'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered '1'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:16', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered 'None (1)'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '0d0c06f8-6525-4412-a023-190ce2fd8702'	System	26 Sep 2020 01:56:44
User entered '25 Sep 2020 20:56'	System	26 Sep 2020 01:56:44

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 3'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'd026d51d-bcab-4ba4-8d6c-27a1ec34ec3b'	System	27 Sep 2020 01:29:11
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 01:29:11

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:31', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'd026d51d-bcab-4ba4-8d6c-27a1ec34ec3b'	System	27 Sep 2020 01:29:11
User entered 'No (N)'	System	27 Sep 2020 01:29:11

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:43', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'd026d51d-bcab-4ba4-8d6c-27a1ec34ec3b'	System	27 Sep 2020 01:29:11
User entered 'No (N)'	System	27 Sep 2020 01:29:11

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:28:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'd026d51d-bcab-4ba4-8d6c-27a1ec34ec3b'	System	27 Sep 2020 01:29:11
User entered 'None (1)'	System	27 Sep 2020 01:29:11

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:08', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'd026d51d-bcab-4ba4-8d6c-27a1ec34ec3b'	System	27 Sep 2020 01:29:11
User entered '26 Sep 2020 20:29'	System	27 Sep 2020 01:29:11

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 4'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:21:57', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b8966d20-3e0f-447e-b8c3-ffabc3ed66b8'	System	28 Sep 2020 01:22:35
User entered 'None (1)'	System	28 Sep 2020 01:22:35

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:01', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b8966d20-3e0f-447e-b8c3-ffabc3ed66b8'	System	28 Sep 2020 01:22:35
User entered 'No (N)'	System	28 Sep 2020 01:22:35

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:04', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b8966d20-3e0f-447e-b8c3-ffabc3ed66b8'	System	28 Sep 2020 01:22:35
User entered 'No (N)'	System	28 Sep 2020 01:22:35

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:19', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b8966d20-3e0f-447e-b8c3-ffabc3ed66b8'	System	28 Sep 2020 01:22:35
User entered 'None (1)'	System	28 Sep 2020 01:22:35

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b8966d20-3e0f-447e-b8c3-ffabc3ed66b8'	System	28 Sep 2020 01:22:35
User entered '27 Sep 2020 20:22'	System	28 Sep 2020 01:22:35

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 5'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:03', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '37493eda-a773-4fc0-8cfd-6dfef0ba51c3'	System	29 Sep 2020 03:35:25
User entered 'None (1)'	System	29 Sep 2020 03:35:25

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:07', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '37493eda-a773-4fc0-8cfd-6dfef0ba51c3'	System	29 Sep 2020 03:35:25
User entered 'No (N)'	System	29 Sep 2020 03:35:25

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:10', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '37493eda-a773-4fc0-8cfd-6dfef0ba51c3'	System	29 Sep 2020 03:35:25
User entered 'No (N)'	System	29 Sep 2020 03:35:25

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:14', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '37493eda-a773-4fc0-8cfd-6dfef0ba51c3'	System	29 Sep 2020 03:35:25
User entered 'None (1)'	System	29 Sep 2020 03:35:25

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '37493eda-a773-4fc0-8cfd-6dfef0ba51c3'	System	29 Sep 2020 03:35:25
User entered '28 Sep 2020 22:35'	System	29 Sep 2020 03:35:25

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 6'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:17', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '4f0f1590-7035-4ae9-9d26-27fc0a83df09'	System	30 Sep 2020 04:52:32
User entered 'None (1)'	System	30 Sep 2020 04:52:32

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '4f0f1590-7035-4ae9-9d26-27fc0a83df09'	System	30 Sep 2020 04:52:32
User entered 'No (N)'	System	30 Sep 2020 04:52:32

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:51:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '4f0f1590-7035-4ae9-9d26-27fc0a83df09'	System	30 Sep 2020 04:52:32
User entered 'No (N)'	System	30 Sep 2020 04:52:32

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '4f0f1590-7035-4ae9-9d26-27fc0a83df09'	System	30 Sep 2020 04:52:32
User entered 'None (1)'	System	30 Sep 2020 04:52:32

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:28', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '4f0f1590-7035-4ae9-9d26-27fc0a83df09'	System	30 Sep 2020 04:52:32
User entered '29 Sep 2020 23:52'	System	30 Sep 2020 04:52:32

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 7'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:18', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:24', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:30', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:32', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'None (0)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:38', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered 'No (N)'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T13:23:47', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: 'b7b4e3cd-70f8-4679-89b9-c28ab3bcf3c6'	System	24 Sep 2020 18:24:26
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 18:24:26

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 13:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 15:30'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:15', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:20', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:23', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:30', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:34', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'None (0)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:42', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered 'No (N)'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-24T20:33:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '660af174-11e9-4346-acc3-69baa48e1635'	System	25 Sep 2020 01:33:56
User entered '24 Sep 2020 20:33'	System	25 Sep 2020 01:33:56

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '24 Sep 2020 16:25'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 2'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:49', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:56:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:57:02', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:57:06', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'None (0)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:57:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered 'No (N)'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-25T20:57:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '63ae7eeb-34a4-4bd3-82cd-5c025c97e6e4'	System	26 Sep 2020 01:57:23
User entered '25 Sep 2020 20:57'	System	26 Sep 2020 01:57:23

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 3'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:21', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:24', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:27', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:30', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:36', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'None (0)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:29:50', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered 'No (N)'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-26T20:30:00', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6dc1b6c7-0f1d-4e01-b7ec-956eff6fa464'	System	27 Sep 2020 01:30:05
User entered '26 Sep 2020 20:30'	System	27 Sep 2020 01:30:05

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 4'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:38', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:41', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:44', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:48', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:22:59', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'None (0)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:23:05', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered 'No (N)'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-27T20:23:15', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '3263dbd2-3c3e-4cfc-b305-252b4e546176'	System	28 Sep 2020 01:23:17
User entered '27 Sep 2020 20:23'	System	28 Sep 2020 01:23:17

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 5'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:29', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:31', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:35', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:37', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:40', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:43', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'None (0)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:48', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered 'No (N)'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-28T22:35:57', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '08ab0c40-f516-402d-b67e-4bcc6670bd23'	System	29 Sep 2020 03:35:59
User entered '28 Sep 2020 22:35'	System	29 Sep 2020 03:35:59

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 6'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:36', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:39', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:43', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:46', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:49', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:52', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'None (0)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:52:56', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered 'No (N)'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-09-29T23:53:05', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '96da2398-052e-4e26-9b7c-fae0c65426cb'	System	30 Sep 2020 04:53:08
User entered '29 Sep 2020 23:53'	System	30 Sep 2020 04:53:08

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	24 Sep 2020 17:44:42
User entered 'Day 7'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

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)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:44:42

US3912024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:44:42

US3912024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 15:01:24

US3912024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '2 Oct 2020'	Tina Rountree (b) (4)	02 Oct 2020 15:01:24

US3912024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Contact Made (CONTACT MADE)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 15:01:24

US3912024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered empty.	Tina Rountree (b) (4)	02 Oct 2020 15:01:24

US3912024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:42:41
User entered 'Yes (Y)'	Tina Rountree (b) (4)	02 Oct 2020 15:01:29

US3912024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	02 Oct 2020 15:01:29

US3912024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:43:41
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	08 Oct 2020 17:14:18

US3912024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:43:41
User entered '8 Oct 2020'	Sandra Clancy (b) (4)	08 Oct 2020 17:14:18

US3912024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:43:41
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	08 Oct 2020 17:14:18

US3912024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:43:41
User entered empty.	Sandra Clancy (b) (4)	08 Oct 2020 17:14:18

US3912024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:43:46
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	08 Oct 2020 17:14:25

US3912024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	08 Oct 2020 17:14:25

US3912024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:53:53
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	15 Oct 2020 15:44:33

US3912024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 15:53:53
User entered '15 Oct 2020'	Sandra Clancy (b) (4)	15 Oct 2020 15:44:33

US3912024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 15:53:53
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4)	15 Oct 2020 15:44:33

US3912024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 15:53:53
User entered empty.	Sandra Clancy (b) (4)	15 Oct 2020 15:44:33

US3912024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 15:54:12
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	15 Oct 2020 15:44:37

US3912024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	15 Oct 2020 15:44:37

US3912024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:57:11
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:45:16

US3912024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:57:11
User entered '22 Oct 2020'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:45:16

US3912024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 15:57:11
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	23 Oct 2020 21:45:16

US3912024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'VISIT3'	System	23 Oct 2020 21:45:16

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '22 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '10:41'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '22 Oct 2020 10:41'	System	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '36.2' C	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '63'	Mia Rountree (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'bpm'	System	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '12'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'breaths/min'	System	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '114'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User entered '67'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered 'mmHg'	System	23 Oct 2020 21:46:25

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59

US3912024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59

US3912024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:23
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:41

US3912024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:23
User entered '22 Oct 2020'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:46:41

US3912024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:04:38
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:47:00

US3912024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:04:38
User entered '22 Oct 2020'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:47:00

US3912024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:04:38
User entered '12:27'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:47:00

US3912024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered '22 Oct 2020 12:27'	System	23 Oct 2020 21:47:00

US3912024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:48:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:08:18
User closed query 'Please confirm response. ' (Site from CRA).		30 Mar 2021 19:08:03
Query 'Please confirm response. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	30 Mar 2021 17:56:17
DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4)	30 Mar 2021 17:55:56
Signature has been broken.	(b) (4) Sandra Clancy (b) (4)	30 Mar 2021 17:55:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	30 Mar 2021 17:55:56
User opened query 'Please confirm response. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:49:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:04:49
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:47:04

US3912024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:59
User entered empty.	System	30 Mar 2021 17:55:56
User entered '1'	System	23 Oct 2020 21:47:04

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 64'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-10-28T11:33:11', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6636d6f4-eaa2-48b1-a385-e3f90a28e1de'	System	28 Oct 2020 16:33:35
User entered 'No (N)'	System	28 Oct 2020 16:33:35

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-10-28T11:33:22', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6636d6f4-eaa2-48b1-a385-e3f90a28e1de'	System	28 Oct 2020 16:33:35
User entered 'No (N)'	System	28 Oct 2020 16:33:35

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ad2f93b9e005ef32)', Time: '2020-10-28T11:33:33', User OID: 'PatientReportedOutcome (US3912024)', ODM File OID: '6636d6f4-eaa2-48b1-a385-e3f90a28e1de' User entered '28 Oct 2020 11:33:33'	System	28 Oct 2020 16:33:35
	System	28 Oct 2020 16:33:35

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:41:31
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 71'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered 'Day 78'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47

US3912024

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 19:22:07

US3912024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:47
Data entry locked.	System	28 Aug 2020 19:22:07
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 19:22:07

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:11:48
DataPoint Un-verified.		03 Nov 2020 18:20:45
User entered '22 Oct 2020' reason for change: Data Entry Error		03 Nov 2020 18:20:45
DataPoint Verified.		28 Oct 2020 17:48:36
User entered '27 Oct 2020'		27 Oct 2020 18:52:03

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:11:50
DataPoint Un-verified.		03 Nov 2020 18:21:29
User entered '11:25' reason for change: Data Entry Error		03 Nov 2020 18:21:29
DataPoint Verified.		28 Oct 2020 17:48:36
User entered '11:00'		27 Oct 2020 18:52:03

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '22 Oct 2020 11:25'	System	03 Nov 2020 18:21:29
User entered '22 Oct 2020 11:00'	System	03 Nov 2020 18:20:45
User entered '27 Oct 2020 11:00'	System	27 Oct 2020 18:52:03

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:24:48
User closed query 'Per CRF Guidelines, 'Clinical Visit - Scheduled' is an option for Type of Contact. Please clarify reason for 'Clinical visit - Unscheduled' or correct response to 'Clinical Visit - Scheduled'.' (Site from CRA).		11 Nov 2020 00:24:46
Query 'Per CRF Guidelines, 'Clinical Visit - Scheduled' is an option for Type of Contact. Please clarify reason for 'Clinical visit - Unscheduled' or correct response to 'Clinical Visit - Scheduled'.' answered with 'data corrected. Subject was in for day 57 when it was converted to an illness visit. ' (Site from CRA).		11 Nov 2020 00:24:04
DataPoint Un-verified.		11 Nov 2020 00:24:00
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error		11 Nov 2020 00:24:00
User opened query 'Per CRF Guidelines, 'Clinical Visit - Scheduled' is an option for Type of Contact. Please clarify reason for 'Clinical visit - Unscheduled' or correct response to 'Clinical Visit - Scheduled'.' (Site from CRA).		10 Nov 2020 17:11:38
User closed query 'Please clarify response. Per source documentation, subject's V3D57 visit occurred on 22Oct2020. Thank you!' (Site from CRA).		10 Nov 2020 17:11:38
Query 'Please clarify response. Per source documentation, subject's V3D57 visit occurred on 22Oct2020. Thank you!' answered with 'verified correct that V3D57 visit was 22oct2020.' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 02:17:28
User opened query 'Please clarify response. Per source documentation, subject's V3D57 visit occurred on 22Oct2020. Thank you!' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:12:21
DataPoint Verified.		28 Oct 2020 17:48:36

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	27 Oct 2020 18:52:03

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:45

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:48:36
User entered 'Yes (Y)'		27 Oct 2020 18:52:03

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '17 Oct 2020'		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:52:45

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '18 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '19 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '20 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '21 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '22 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '23 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '24 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '25 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '26 Oct 2020'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered '1'		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:58
User entered empty.		27 Oct 2020 18:54:29

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered '27 Oct 2020'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered '0'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered '97'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '%'	System	27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered '36.8' C		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'Mild (Mild)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'Mild (Mild)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'Mild (Mild)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'Mild (Mild)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:50:56
User entered 'None (None)'		27 Oct 2020 18:55:39

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered '28 Oct 2020'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered '0'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:15
User entered '98'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '%'	System	03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:13
User entered '98.5' F		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:21
User entered 'Mild (Mild)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:29
User entered '29 Oct 2020'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered '0'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:46
User entered '98'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '%'	System	03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:50
User entered '97.1' F		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:24:56
User entered 'None (None)'		03 Nov 2020 18:24:01

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:32
User entered '27 Oct 2020'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:41
User entered 'Yes (Y)'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:35
User entered 'No (N)'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:37
User entered '27 Oct 2020'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:43
User entered empty.		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:34
User entered 'No (N)'		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:43
User entered empty.		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:43
User entered empty.		03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:45

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	03 Nov 2020 18:19:47

US3912024

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:19:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 21:11:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	27 Jan 2021 14:53:48

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 3 (Day 3)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:38
User entered 'Yes (Y)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:38
User entered '29 Oct 2020'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 5 (Day 5)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 7 (Day 7)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 9 (Day 9)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 14 (Day 14)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 21 (Day 21)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:45

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User accepted default value 'Day 28 (Day 28)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:27:59
User entered empty.		03 Nov 2020 18:20:08

US3912024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:20
User entered 'Yes (Y)'		27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:20
User entered '27 Oct 2020'		27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:20
User entered 'Clinic (Clinic)'		27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'SICKD1'	System	27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered 'Yes (Y)'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '27 Oct 2020'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '11:10'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '27 Oct 2020 11:10'	System	27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '70' in	(b) (4), (b) (6)	27 Oct 2020 18:56:48
DataPoint set to visible.	System	27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '134.0' lb	(b) (4), (b) (6)	27 Oct 2020 18:56:48
DataPoint set to visible.	System	27 Oct 2020 18:56:10

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '36.8' C		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered 'Oral (Oral)'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered empty.		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '65'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'bpm'	System	27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '17'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'breaths/min'	System	27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '111'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:51:39
User entered '66'		27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered 'mmHg'	System	27 Oct 2020 18:56:48

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:52:24
User entered 'Yes (Y)'		27 Oct 2020 18:57:03

US3912024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:52:24
User entered '27 Oct 2020'		27 Oct 2020 18:57:03

US3912024

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:45

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:52:35
User entered 'Yes (Y)'		27 Oct 2020 18:57:14

US3912024

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:52:35
User entered '27 Oct 2020'		27 Oct 2020 18:57:14

US3912024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:19:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:05:11
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:57:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Rhonchi, LLT: Rhonchi - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 20:33:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:06:12
Data point term sent to Coder	System	23 Oct 2020 13:59:45
User entered 'Faint rhonchi lower lobes'	Mia Rountree (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '22 Oct 2020'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:24
DataPoint Un-verified.		27 Oct 2020 18:59:21
User entered 'No (N)' reason for change: Data Entry Error		27 Oct 2020 18:59:21
DataPoint Verified.		26 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:20
DataPoint Un-verified.		27 Oct 2020 18:59:21
User entered '27 Oct 2020' reason for change: Data Entry Error		27 Oct 2020 18:59:21
DataPoint Verified.		26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:59:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:59:56
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 14:59:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 13:59:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:59:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:59:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 14:59:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 13:59:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '1'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered '0'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
DataPoint Un-verified.		27 Oct 2020 18:59:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		27 Oct 2020 18:59:21
Data Entry Error		
DataPoint Verified.		26 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:59:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:59:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 14:59:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 13:59:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:06:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	23 Oct 2020 14:59:56

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	23 Oct 2020 13:59:10

US3912024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:02:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:02:26
Data point term sent to Coder	System	27 Oct 2020 19:01:02
User entered 'Cough'	(b) (4), (b) (6)	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '17 Oct 2020'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '19 Oct 2020'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Grade 1/Mild (Grade 1/Mild)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Related (NOT RELATED)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Related (NOT RELATED)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Applicable (NOT APPLICABLE)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 19:00:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:00:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 19:00:31
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	27 Oct 2020 19:00:31

US3912024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:03:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:03:30
Data point term sent to Coder	System	27 Oct 2020 19:02:03
User entered 'vomiting'	(b) (4), (b) (6)	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '17 Oct 2020'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '19 Oct 2020'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'No (N)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Related (NOT RELATED)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Related (NOT RELATED)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Not Applicable (NOT APPLICABLE)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 19:03:06
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:03:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 19:01:44
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered '0'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:53:48
User entered empty.		27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	27 Oct 2020 19:01:44

US3912024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:29:24
Reviewed for Safety.		16 Nov 2020 23:38:21
User entered 'USA-US211-2020-mRNA-1273-P301000006'	System	16 Nov 2020 23:35:36
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 23:35:36

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:33:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:19:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:19:43
Data point term sent to Coder	System	13 Nov 2020 17:26:42
User entered 'Flank Pain (Left)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:33:49
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:33:53
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:33:55
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:34:01
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:34:23
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:34:26
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:34:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:34:35
User entered 'Yes (Y)'	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:33:07
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).		17 Nov 2020 18:24:03
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission date added' (Site from System).	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:26:30
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	13 Nov 2020 17:25:46
User entered '1'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:41
User entered '3 Nov 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	13 Nov 2020 17:26:10
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:37
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:34
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:30
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:23
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '1'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:17
User entered '1'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:12:17
DataPoint Un-verified.	Sandra Clancy (b) (4)	23 Dec 2020 19:46:36
User entered 'SUBJECT WENT TO ER ON 03NOV2020 FOR FLANK PAIN. SUBJECT DIAGNOSED WITH A LEFT RENAL STONE THAT REQUIRED RENAL STENT PLACEMENT. The subject was initially assessed on 31Oct2020 with ureteral stones and was discharged with recommendation to follow up with PCP. Subject did not have follow up but abdominal pain had worsened and he returned to the ER. A CT of abdomen/pelvis was performed on 03Nov revealing obstructing proximal left ureteral stones measuring up to 9mm. Other findings include mild hydronephrosis, and increased left renal edema; findings concerning for pyelonephritis. Urology was consulted and subject was taken to the OR for ureteral stent placement.'	(b) (4) Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:46:36
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:12
User entered 'Subject went to ER on 03NOV2020 for flank pain. Subject diagnosed with a left renal stone that required renal stent placement.'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	13 Nov 2020 17:25:46

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
Reviewed for Safety.		16 Nov 2020 23:38:35
User entered 'USA-US211-2020-mRNA-1273-P301000006'		16 Nov 2020 23:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:00:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer perforation, LLT: Duodenal ulcer perforated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 20:19:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 20:19:20
Data point term sent to Coder	System	29 Nov 2020 17:09:00
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:08:51
Coding entries removed.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:08:51
User entered 'Perforated Duodenal ulcer' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:08:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:34:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Intestinal ulcers and perforation NEC, PT: Intestinal perforation, LLT: Bowel perforation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:47:47
Data point term sent to Coder	System	13 Nov 2020 17:31:55
User entered 'Bowel Perforation'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:34:58
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:36:10
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:36:12
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:00:38
DataPoint Un-verified.	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
User entered '8 Nov 2020' reason for change: Data Entry Error	(b) (4) Tina Rountree (b) (4)	29 Nov 2020 17:08:51
User closed query 'Per CDM: Start date should not be left blank. Please review and update, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 04:14:00
DataPoint Verified.		19 Nov 2020 16:54:43
Query 'Per CDM: Start date should not be left blank. Please review and update, else clarify. ' answered with 'Start date is unknown' (Site from DM).	Mia Rountree (b) (4) (b) (4)	18 Nov 2020 17:59:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 23:54:56
User opened query 'Per CDM: Start date should not be left blank. Please review and update, else clarify. ' (Site from DM).		17 Nov 2020 23:54:53
Query 'Data is required. Please complete.' answered with 'Start date is unknown ' (Site from System).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 22:46:51
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:50
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:31:00
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:44:57
DataPoint Un-verified.	Mia Rountree (b) (4)	20 Nov 2020 17:44:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Mia Rountree (b) (4)	20 Nov 2020 17:44:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	20 Nov 2020 17:44:41
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:30:57
User closed query 'Per Adverse Event Form #5, Bowel Perforation End Date was 08Nov2020. Please clarify or update EDC. Thank you!' (Site from CRA). Query 'Per Adverse Event Form #5, Bowel Perforation End Date was 08Nov2020. Please clarify or update EDC. Thank you!' answered with 'Data updated' (Site from CRA).	Mia Rountree (b) (4)	20 Nov 2020 17:46:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:46:27
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	20 Nov 2020 17:46:27
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	20 Nov 2020 17:44:41
DataPoint Un-verified.	Mia Rountree (b) (4)	20 Nov 2020 17:44:41
User entered '08 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	20 Nov 2020 17:44:41
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User opened query 'Per Adverse Event Form #5, Bowel Perforation End Date was 08Nov2020. Please clarify or update EDC. Thank you!' (Site from CRA).		19 Nov 2020 16:37:06
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:17
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:26
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).		17 Nov 2020 18:36:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission date added, subject is still hospitalized' (Site from System).	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:34:01
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	13 Nov 2020 17:31:50
User entered '1'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Form: Adverse Events (5)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:30
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:00:42
User closed query 'Per CDM: Hospital Discharge date is missing. Please update or else clarify. Thank you.' (Site from DM).		01 Dec 2020 10:35:12
Query 'Per CDM: Hospital Discharge date is missing. Please update or else clarify. Thank you.' answered with 'Updated with date of death, subject was never discharged.' (Site from DM).	Tina Rountree (b) (4)	29 Nov 2020 16:41:52
DataPoint Un-verified.	(b) (4)	
	Tina Rountree (b) (4)	29 Nov 2020 16:41:30
User entered '22 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Tina Rountree (b) (4)	29 Nov 2020 16:41:30
User opened query 'Per CDM: Hospital Discharge date is missing. Please update or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:18:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4)	13 Nov 2020 17:31:50
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:34
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:36
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:38
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:37:41
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per CDM: Concomitant procedure is marked or recorded. However There is no record of concomitant procedure in respective Concomitant procedure form. Please update or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:50:28
Query 'Per CDM: Concomitant procedure is marked or recorded. However There is no record of concomitant procedure in respective Concomitant procedure form. Please update or else clarify. Thank you.' answered with 'graham patch' (Site from DM).	Sandra Clancy (b) (4)	10 Dec 2020 20:39:37
User opened query 'Per CDM: Concomitant procedure is marked or recorded. However There is no record of concomitant procedure in respective Concomitant procedure form. Please update or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:20:32
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '1'	Tina Rountree (b) (4)	13 Nov 2020 17:31:50

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:02:05
DataPoint Un-verified.	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:47:27
DataPoint Un-verified.	Mia Rountree (b) (4)	20 Nov 2020 17:46:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mia Rountree (b) (4)	20 Nov 2020 17:46:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:37:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4)	13 Nov 2020 17:31:50

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:02:48
DataPoint Un-verified.	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
User entered 'anemia' reason for change: Data Entry Error	(b) (4) Tina Rountree (b) (4)	29 Nov 2020 17:08:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Nov 2020 17:31:50

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per DM CLR: Narrative indicates that there were findings of Ascites, Bibasal Pulmonary Infiltrates and Pleural Effusion, and Soft Tissue Anasarca. However, there are no corresponding AE record that match the information. Please review and update to these findings as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 09:04:27
User closed query 'Per DM CLR: Narrative indicates that the subject had several CT Scans on different dates and an Exploratory Laparotomy was also performed. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).		29 Jan 2021 09:04:24
Query 'Per DM CLR: Narrative indicates that there were findings of Ascites, Bibasal Pulmonary Infiltrates and Pleural Effusion, and Soft Tissue Anasarca. However, there are no corresponding AE record that match the information. Please review and update to these findings as appropriate. Otherwise, provide clarification.' answered with 'events have been updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:50:03
Query 'Per DM CLR: Narrative indicates that the subject had several CT Scans on different dates and an Exploratory Laparotomy was also performed. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'con procedures listed' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:15:26

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that there were findings of Ascites, Bibasal Pulmonary Infiltrates and Pleural Effusion, and Soft Tissue Anasarca. However, there are no corresponding AE record that match the information. Please review and update to these findings as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 13:13:12
User opened query 'Per DM CLR: Narrative indicates that the subject had several CT Scans on different dates and an Exploratory Laparotomy was also performed. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).		16 Jan 2021 13:12:20
DataPoint Verified.		06 Jan 2021 16:12:37

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HOSPITALIZED FOR COMPLICATIONS RELATED TO RENAL STONE. CHARGE NURSE AT HOSPITAL REPORTED BOWEL PERFORATION VIA PHONE CONVERSATION WITH CRC, PENDING MEDICAL RECORDS TO OBTAIN DATE AND CAUSE OF PERFORATION. UPDATE - AFTER FURTHER REVIEW OF MEDICAL RECORDS CHANGED TITLE OF ADVERSE EVENT TO PERFORATED DUODENAL ULCER. ON 05NOV POST-OP DAY 1, THE SUBJECT REPORTS ONGOING ABDOMINAL PAIN; LATER SAME DAY PLATELETS DROP TO 59K, TRENDING DOWN 79K-73K-59K. WHILE THERE IS NO REPORTED SIGNS OF ACTIVE BLEEDING; SUBJECT HAS ANOTHER CT OF ABD/PELVIS ON 08NOV. RESULTS REVEAL INCREASED ATELECTASIS-CONSOLIDATION BOTH LOWER LOBES WITH NEW PATCHY INFILTRATE IN POSTERIOR RIGHT UPPER LOBE. MODERATELY LARGE VOLUME OF INTRAABDOMINAL FREE FLUID W/LARGE AMOUNT OF PNEUMOPERITONEUM NOTED. PERFORATION IS SUSPECTED BUT SITE COULD NOT BE IDENTIFIED BY CT. SUBJECT WAS TAKEN TO THE OR ON 08NOV, EXPLORATORY LAPAROTOMY WAS PERFORMED WITH CLOSURE OF DUODENAL ULCER WITH GRAHAM PATCH, EXTENSIVE LYSIS OF DHESIONS, AND DRAINAGE OF PERITONEAL ABSCESES. A DRAIN WAS BROUGHT OUT THROUGH INCISION IN RIGHT UPPER QUADRANT AND THEN PLACED POSTERIOR SUPERIOR TO THE ACTUAL ULCER. FOLLOW UP CT WAS PERFORMED TO ASSURE NO LEAK OR OBSTRUCTION. HOWEVER, ON 13NOV CONTINUED TO HAVE LEAKING OF DARK BROWN FLUID FROM RIGHT SIDE JP-SUBJECT UNDERGOES CT OF ABD/ PELVIS WITH FOLLOWING FINDINGS:	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 20:22:58

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
INTERVAL PLACEMENT OF A SURGICAL DRAIN IN SUBHEPATIC SPaCE WITH DIMINISHING VOLUME OF ASCITES. RESIDEUAL GRAVITY DEPENDENT FLUID IS NOTED IN PELVIS. POSTSURGICAL CHANGE IN THE VENTRAL ABDOMINAL WALL, EDEMATOUS CHANGES IN THE OMENTUM. THERE ARE SMALL LOCULATIONS OF FLUID ADJACENT TO THE DESCENDING COLON; WORSENING BIBASAL PULMONARY INFILTRATES AND PLEURAL EFFUSIONS; WORSENING SOFT TISSUE ANASARCA.'		
reason for change: Data Entry Error		

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HOSPITALIZED FOR COMPLICATIONS RELATED TO RENAL STONE. CHARGE NURSE AT HOSPITAL REPORTED BOWEL PERFORATION VIA PHONE CONVERSATION WITH CRC, PENDING MEDICAL RECORDS TO OBTAIN DATE AND CAUSE OF PERFORATION. UPDATE - AFTER FURTHER REVIEW OF MEDICAL RECORDS CHANGED TITLE OF ADVERSE EVENT TO PERFORATED DUODENAL ULCER. ON 05NOV POST-OP DAY 1, THE SUBJECT REPORTS ONGOING ABDOMINAL PAIN; LATER SAME DAY PLATELETS DROP TO 59K, TRENDING DOWN 79K-73K-59K. WHILE THERE IS NO REPORTED SIGNS OF ACTIVE BLEEDING; SUBJECT HAS ANOTHER CT OF ABD/PELVIS ON 08NOV. RESULTS REVEAL INCREASED ATELECTASIS-CONSOLIDATION BOTH LOWER LOBES WITH NEW PATCHY INFILTRATE IN POSTERIOR RIGHT UPPER LOBE. MODERATELY LARGE VOLUME OF INTRAABDOMINAL FREE FLUID W/LARGE AMOUNT OF PNEUMOPERITONEUM NOTED. PERFORATION IS SUSPECTED BUT SITE COULD NOT BE IDENTIFIED BY CT. SUBJECT WAS TAKEN TO THE OR ON 08NOV, EXPLORATORY LAPAROTOMY WAS PERFORMED WITH CLOSURE OF DUODENAL ULCER WITH GRAHAM PATCH, EXTENSIVE LYSIS OF DHESIONS, AND DRAINAGE OF PERITONEAL ABSCESES. A DRAIN WAS BROUGHT OUT THROUGH INCISION IN RIGHT UPPER QUADRANT AND THEN PLACED POSTERIOR SUPERIOR TO THE ACTUAL ULCER. FOLLOW UP CT WAS PERFORMED TO ASSURE NO LEAK OR OBSTRUCTION. HOWEVER, ON 13NOV CONTINUED TO HAVE LEAKING OF DARK BROWN FLUID FROM RIGHT SIDE JP-SUBJECT UNDERGOES CT OF ABD/ PELVIS WITH FOLLOWING FINDINGS:	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 20:21:36

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
INTERVAL PLACEMENT OF A SURGICAL DRAIN IN SUBHEPATIC SPCE WITH DIMINISHING VOLUME OF ASCITES. RESIDEUAL GRAVITY DEPENDENT FLUID IS NOTED IN PELVIS. POSTSURGICAL CHANGE IN THE VENTRAL ABDOMINAL WALL, EDEMATOUS CHANGES IN THE OMENTUM. THERE ARE SMALL LOCuLATIONS OF FLUID ADJACENT TO THE DESCENDING COLON; WORSENING BIBASAL PULMONARY INFILTRATES AND PLEURAL EFFUSIONS; WORSENING SOFT TISSUE ANASARCA.'		
reason for change: Data Entry Error		

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HOSPITALIZED FOR COMPLICATIONS RELATED TO RENAL STONE. CHARGE NURSE AT HOSPITAL REPORTED BOWEL PERFORATION VIA PHONE CONVERSATION WITH CRC, PENDING MEDICAL RECORDS TO OBTAIN DATE AND CAUSE OF PERFORATION. UPDATE - AFTER FURTHER REVIEW OF MEDICAL RECORDS CHANGED TITLE OF ADVERSE EVENT TO PERFORATED DUODENAL ULCER. ON 05NOV POST-OP DAY 1, THE SUBJECT REPORTS ONGOING ABDOMINAL PAIN; LATER SAME DAY PLATELETS DROP TO 59K, TRENDING DOWN 79K-73K-59K. WHILE THERE IS NO REPORTED SIGNS OF ACTIVE BLEEDING; SUBJECT HAS ANOTHER CT OF ABD/PELVIS ON 08NOV. RESULTS REVEAL INCREASED ATELECTASIS-CONSOLIDATION BOTH LOWER LOBES WITH NEW PATCHY INFILTRATE IN POSTERIOR RIGHT UPPER LOBE. MODERATELY LARGE VOLUME OF INTRAABDOMINAL FREE FLUID W/LARGE AMOUNT OF PNEUMOPERITONEUM NOTED. PERFORATION IS SUSPECTED BUT SITE could NOT BE IDENTIFIED BY CT. SUBJECT WAS TAKEN TO THE OR ON 08NOV, EXPLORATORY LAPAROTOMY WAS PERFORMED WITH CLOSURE OF DUODENAL ULCER WITH GRAHAM PATCH, EXTENSIVE LYSIS OF DHESIONS, AND DRAINAGE OF PERITONEAL ABSCESES. A drain was brought out through incision in right upper quadrant and then placed posterior superior to the actual ulcer. Follow up CT was performed to assure no leak or obstruction. However, on 13Nov continued to have leaking of dark brown fluid from right side JP-subject undergoes CT of abd/ pelvis with following findings: interval placement of a surgical drain in subhepatic spce with diminishing volume of ascites. Residual gravity dependent fluid is noted in pelvis.	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 20:20:53

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Postsurgical change in the ventral abdominal wall, edematous changes in the omentum. There are small loculations of fluid adjacent to the descending colon; worsening bibasal pulmonary infiltrates and pleural effusions; worsening soft tissue anasarca.' reason for change: Data Entry Error DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 20:04:33
User entered 'SUBJECT HOSPITALIZED FOR COMPLICATIONS RELATED TO RENAL STONE. CHARGE NURSE AT HOSPITAL REPORTED BOWEL PERFORATION VIA PHONE CONVERSATION WITH CRC, PENDING MEDICAL RECORDS TO OBTAIN DATE AND CAUSE OF PERFORATION.	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 20:04:33
UPDATE - AFTER FURTHER REVIEW OF MEDICAL RECORDS CHANGED TITLE OF ADVERSE EVENT TO PERFORATED DUODENAL ULCER. On 05Nov post-op day 1, the subject reports ongoing abdominal pain; later same day platelets drop to 59k, trending down 79k-73k-59k. While there is no reported signs of active bleeding; subject has another CT of abd/pelvis on 08Nov. Results reveal increased atelectasis-consolidation both lower lobes with new patchy infiltrate in posterior right upper lobe. Moderately large volume of intraabdominal free fluid w/large amount of pneumoperitoneum noted. Perforation is suspected but site cannot be identified by CT. Subject was taken to the OR on 08Nov, exploratory laparotomy was performed with closure of duodenal ulcer with Graham patch, extensive lysis of dhensions, and drainage of peritoneal abscesses.' reason for change: Data Entry Error User closed query ' PV Query: Please confirm etiology of perforated duodenum.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Dec 2020 15:17:16

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Query ' PV Query: Please confirm etiology of perforated duodenum.' answered with 'Comorbidities for this subject include Crohns disease, multiple/recurrent small bowel obstruction/resection, colon resection, nonalcoholic cirrhosis s/p TIPS, and hepatic stent. On Nov 8 the subject returned to the OR for exploratory laparotomy; this was initiated due to CT findings of acute massive free intraperitoneal air and fluid. Post op results: closure of duodenal ulcer with Graham patch, extensive lysis of adhesions, and drainage of peritoneal abscesses.' (Site from Safety).	Sandra Clancy (b) (4)	18 Dec 2020 21:08:15
User opened query ' PV Query: Please confirm etiology of perforated duodenum.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 22:14:14
		01 Dec 2020 20:18:18
DataPoint Un-verified.	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
	(b) (4)	
User entered 'SUBJECT HOSPITALIZED FOR COMPLICATIONS RELATED TO RENAL STONE. CHARGE NURSE AT HOSPITAL REPORTED BOWEL PERFORATION VIA PHONE CONVERSATION WITH CRC, PENDING MEDICAL RECORDS TO OBTAIN DATE AND CAUSE OF PERFORATION.	Tina Rountree (b) (4)	29 Nov 2020 17:08:51
	(b) (4)	
Update - after further review of medical records changed title of adverse event to Perforated duodenal ulcer.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:38:03
User entered 'Subject hospitalized for complications related to renal stone. Charge nurse at hospital reported bowel perforation via phone conversation with CRC, pending medical records to obtain date and cause of perforation.'	Tina Rountree (b) (4)	13 Nov 2020 17:31:50
	(b) (4)	

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	13 Nov 2020 17:31:50

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	13 Nov 2020 17:31:50

US3912024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	13 Nov 2020 17:31:50

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:22:50
Reviewed for Safety.		27 Nov 2020 14:43:14
User entered 'USA-US211-2020-mRNA-1273-P301000006'		27 Nov 2020 14:43:09

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:22:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Multiple organ dysfunction syndrome, LLT: Multi organ failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 09:04:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 09:04:07
Data point term sent to Coder	System	25 Nov 2020 23:02:34
User entered 'Multisystem Organ Failure'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:01
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:04
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:06
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:08
User entered '20 Nov 2020'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:10
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:03
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 15:44:37
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	31 Dec 2020 15:44:37
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 15:44:21
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:56:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:56:27
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:23:11
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:05
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	31 Dec 2020 15:44:21
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	31 Dec 2020 15:44:21
User entered '22 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	31 Dec 2020 15:44:21
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	31 Dec 2020 15:43:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Dec 2020 15:56:27
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	21 Dec 2020 15:56:27
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:56:27
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:56:27
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	21 Dec 2020 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:20:52
User entered '22 Nov 2020'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:54
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:51
User entered 'Grade 4 (Grade 4)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:50
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:26
User entered '1'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:28
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:29
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	25 Nov 2020 23:04:16
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	25 Nov 2020 23:04:16
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	25 Nov 2020 23:03:29
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	25 Nov 2020 23:03:29
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	25 Nov 2020 23:03:29
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 23:03:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	25 Nov 2020 23:02:11
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:25
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:23
User entered '22 Nov 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 23:04:16
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:22
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	25 Nov 2020 23:03:29
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	25 Nov 2020 23:03:29
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	25 Nov 2020 23:02:11
User entered '1'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:14
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:15
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:16
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:17
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		30 Nov 2020 19:03:13
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Causality assessment updated' (Site from Safety).	Tina Rountree (b) (4) (b) (4)	27 Nov 2020 18:15:38
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Nov 2020 18:15:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Nov 2020 18:15:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	27 Nov 2020 18:15:10
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 17:08:25
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:02:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:10
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Nov 2020 18:15:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Nov 2020 18:15:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	27 Nov 2020 18:15:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:02:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Nov 2020 18:15:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Nov 2020 18:15:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	27 Nov 2020 18:15:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:02:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:07
User entered '0'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

US3912024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per DM CLR-RQ; Site's response noted. However, there is no corresponding ConMed record that is indicate for this AE. Please reconcile and update indication of the corresponding medication/s that were given for this AE as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR-RQ; Site's response noted. However, there is no corresponding ConMed record that is indicate for this AE. Please reconcile and update indication of the corresponding medication/s that were given for this AE as appropriate. Otherwise, clarify.' answered with 'con meds updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:06:06
User opened query 'Per DM CLR-RQ; Site's response noted. However, there is no corresponding ConMed record that is indicate for this AE. Please reconcile and update indication of the corresponding medication/s that were given for this AE as appropriate. Otherwise, clarify.' (Site from DM). User closed query 'Per CDM: Other action taken concomitant medication is marked yes. However there is no record of concomitant medication in the respective eCRF.' (Site from DM).	Sandra Clancy (b) (4)	25 Jan 2021 22:51:50
User opened query 'Per DM CLR-RQ; Site's response noted. However, there is no corresponding ConMed record that is indicate for this AE. Please reconcile and update indication of the corresponding medication/s that were given for this AE as appropriate. Otherwise, clarify.' (Site from DM). User closed query 'Per CDM: Other action taken concomitant medication is marked yes. However there is no record of concomitant medication in the respective eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 13:11:59
Query 'Per CDM: Other action taken concomitant medication is marked yes. However there is no record of concomitant medication in the respective eCRF.' answered with 'con meds have been updated - please review and advise if further information is needed' (Site from DM).	(b) (4)	22 Dec 2020 07:04:56
User opened query 'Per CDM: Other action taken concomitant medication is marked yes. However there is no record of concomitant medication in the respective eCRF.' (Site from DM). DataPoint Verified.	Sandra Clancy (b) (4)	21 Dec 2020 15:57:19
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 07:11:02
	(b) (4)	01 Dec 2020 20:20:05
	Tina Rountree (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:20:04
User entered '1'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:12:54
User closed query 'PV Query: As 'Multisystem organ failure' has a seriousness criteria of Death, please update outcome to Fatal.' (Site from Safety).		04 Jan 2021 14:33:17
Query 'PV Query: As 'Multisystem organ failure' has a seriousness criteria of Death, please update outcome to Fatal.' answered with 'updated per query' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	31 Dec 2020 15:44:55
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	31 Dec 2020 15:43:51
User opened query 'PV Query: As 'Multisystem organ failure' has a seriousness criteria of Death, please update outcome to Fatal.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:36:08
User closed query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #7 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).		22 Dec 2020 06:50:52
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #7 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' answered with 'corrected per query' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:56:44
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:55:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 15:55:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE # outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:12:37
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #3 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.		04 Dec 2020 10:12:24
' canceled (Site from DM).		
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE # outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.		04 Dec 2020 10:10:44
' (Site from DM).		
DataPoint Verified.		01 Dec 2020 20:20:01
User entered 'Fatal (FATAL)'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:19:53
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:19:46
User entered 'Site was informed that subject passed away by family member. Records requested. Obtained minimal new information and are still pending death summary. Very little detail known at this point however, will provide updates as received.'	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	25 Nov 2020 23:02:11

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:42
Reviewed for Safety.		30 Nov 2020 19:25:14
User entered 'USA-US211-2020-mRNA-1273-P301000006'		30 Nov 2020 19:24:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:43
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 17:38:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 17:38:11
Data point term sent to Coder	System	29 Nov 2020 17:37:01
User entered 'acute renal failure'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:23:44
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:11
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:12
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:14
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:16
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 17:36:56

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:42:39
DataPoint Un-verified.	Sandra Clancy (b) (4)	18 Dec 2020 21:09:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:17
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:42:37
User closed query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' (Site from CRA).		18 Dec 2020 21:42:04
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 21:09:48
Query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:09:32
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 21:09:19
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:09:19
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:09:19
User opened query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:48:33
Query 'Per eCRF guidelines v2.0, Page 38: Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. ' canceled (Site from CRA)		09 Dec 2020 17:48:28
User opened query 'Per eCRF guidelines v2.0, Page 38: Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. ' (Site from CRA).		01 Dec 2020 21:09:17
DataPoint Verified.		01 Dec 2020 20:24:19

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	01 Dec 2020 10:09:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'end date updated' (Site from System).	Tina Rountree (b) (4)	29 Nov 2020 17:52:50
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	29 Nov 2020 17:37:26
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Nov 2020 17:37:26
User entered '22 Nov 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Nov 2020 17:37:26
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Nov 2020 17:36:56
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Form: Adverse Events (8)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:21
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:24
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:26
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:27
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered '1'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:29
User entered '3 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:32
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:33
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

US3912024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

US3912024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:35
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:37
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:24:38
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	30 Mar 2021 15:39:24
User signature succeeded.	Mark Hutchens (b) (4)	30 Mar 2021 13:43:42
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
User entered '0' reason for change: Per Query Resolution	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:13:19
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		28 Dec 2020 16:29:42
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	28 Dec 2020 16:28:35
DataPoint Un-verified.	Sandra Clancy (b) (4)	28 Dec 2020 16:28:35
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4)	28 Dec 2020 16:28:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:10:48
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	30 Mar 2021 15:39:27
User signature succeeded.	Mark Hutchens (b) (4)	30 Mar 2021 13:43:42
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
User entered '1' reason for change: New Information	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:54:48
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:13:20
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).		29 Dec 2020 12:31:55
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.'	Sandra Clancy (b) (4)	28 Dec 2020 16:29:52
answered with 'corrected' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Sandra Clancy (b) (4)	28 Dec 2020 16:28:35
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	28 Dec 2020 16:28:35
	(b) (4)	
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:36:05
DataPoint Verified.		01 Dec 2020 20:24:40
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Nov 2020 17:52:26
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 17:36:56
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:22
DataPoint Un-verified.	Sandra Clancy (b) (4)	28 Dec 2020 16:29:42
User entered '0' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	28 Dec 2020 16:29:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:24:43
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:26:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:26:06
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Ultrasound. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Ultrasound. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'con procedures have been updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:06:18
User opened query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Ultrasound. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	Sandra Clancy (b) (4)	25 Jan 2021 22:53:57
	(b) (4), (b) (6)	16 Jan 2021 13:08:32
		06 Jan 2021 16:13:24

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IN ACUTE RENAL FAILURE UPON HOSPITAL ADMISSION. 03NOV THRU 05NOV, CR 3.5, 3.1 AND 3.3 RESPECTIVELY. AN ULTRASOUND PERFORMED 06NOV TO FOLLOW UP ON HYDRONEPHROSIS REVEALED NO EVIDENCE OF HYDRONEPHROSIS. ON 18NOV SUBJECT HAD CHEST X-RAY (1 VIEW):CLINICAL INDICATION NOTED WAS RENAL FAILURE, FLUID OVERLOAD. FINDINGS WERE DEVELOPMENT OF DIFFUSE BILATERAL INTERSTITIAL INFILTRATES OR EDEMA, VOLUME LOSS THE LUNG BASES AND TRACE PLEURAL FLUID AT THE COSTOPHRENIC ANGLES. ON 19NOV CT OF ABD/PELVIS REVEALS THERE ARE DIFFUSE WATER DENSITY, SIMPLE APPEARING LOCULATED COLLECTIONS OF FLUID THROUGHOUT THE PERITONEAL CAVITY, LARGEST OF WHICH EXTENDS FROM THE LEFT UPPER QUADRANT CAUDALLY INTO THE PELVIS; NO ASSOCIATED INFLAMMATORY CHANGES Or FREE AIR. 20NOV CR2.3.' reason for change: Data Entry Error DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 16:27:37
	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 21:09:29

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IN ACUTE RENAL FAILURE UPON HOSPITAL ADMISSION. 03Nov thru 05Nov, Cr 3.5, 3.1 and 3.3 respectively. An ultrasound performed 06Nov to follow up on hydronephrosis revealed no evidence of hydronephrosis. on 18Nov subject had chest x-ray (1 view):clinical indication noted was renal failure, fluid overload. Findings were development of diffuse bilateral interstitial infiltrates or edema, volume loss the lung bases and trace pleural fluid at the costophrenic angles. On 19Nov CT of abd/pelvis reveals there are diffuse water density, simple appearing loculated collections of fluid throughout the peritoneal cavity, largest of which extends from the left upper quadrant caudally into the pelvis; no associated inflammatory changes of free air. 20Nov Cr2.3.' reason for change: Data Entry Error DataPoint Verified.	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 21:09:29
	(b) (4), (b) (6)	01 Dec 2020 20:26:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Nov 2020 17:52:26
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Nov 2020 17:52:26
User entered 'subject in acute renal failure upon hospital admission.' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:52:26
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Nov 2020 17:36:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 17:36:56

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 17:36:56

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 17:36:56

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	29 Nov 2020 17:36:56

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:26:55
Reviewed for Safety.		30 Nov 2020 19:26:25
User entered 'USA-US211-2020-mRNA-1273-P301000006'		30 Nov 2020 19:26:14

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:36:56
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 06:31:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 06:31:48
Data point term sent to Coder	System	29 Nov 2020 18:08:03
User entered 'obstructing nephrolithiasis'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:36:58
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:00
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:01
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:03
User entered '31 Oct 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

Form: Adverse Events (9)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:07:58

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:05
User entered '4 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:08
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:12
User entered '3 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:14
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:15
User entered 'No (N)'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:24
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:26
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:27
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:08:20
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:37
User entered 'subject hospitalized with acute kidney failure secondary to obstructing nephrolithiasis.'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	29 Nov 2020 18:07:58

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:46
Reviewed for Safety.		30 Nov 2020 19:28:37
User entered 'USA-US211-2020-mRNA-1273-P301000006'		30 Nov 2020 19:27:39

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:37:48
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:17:09
Data point term sent to Coder	System	29 Nov 2020 18:16:04
User entered 'thrombocytopenia'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:50
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered 'No (N)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered 'No (N)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:37:51
User entered '3 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:56:37
DataPoint Un-verified.	Sandra Clancy (b) (4)	18 Dec 2020 21:12:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:12:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 13:56:38
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 21:12:41
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Dec 2020 21:12:41
DataPoint Un-verified.	Sandra Clancy (b) (4)	18 Dec 2020 21:12:41
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	18 Dec 2020 21:12:41
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 21:12:08
Query 'Per eCRF Completion Guidelines v2.0, Page 38: AEs that are ongoing at the time of death should not have an end date.' canceled (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:41:53
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:38:51
User opened query 'Per eCRF Completion Guidelines v2.0, Page 38: AEs that are ongoing at the time of death should not have an end date.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:38:49
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57
	(b) (4)	

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:39:59
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	29 Nov 2020 18:16:11
User entered 'Grade 4 (Grade 4)' reason for change:	Tina Rountree (b) (4)	29 Nov 2020 18:16:11
Data Entry Error	(b) (4)	
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	29 Nov 2020 18:15:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:40:01
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:40:28
User entered '1'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:40:30
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Nov 2020 18:16:41
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Nov 2020 18:16:41
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Nov 2020 18:16:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	29 Nov 2020 18:15:57
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:40:22
User entered '3 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:40:23
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:40:25
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:40:26
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	29 Nov 2020 18:16:41
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	29 Nov 2020 18:16:41
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	29 Nov 2020 18:15:57
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:45
User closed query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).		30 Dec 2020 15:39:44
Query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' answered with 'entry corrected; data entry error' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:55:53
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:55:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:55:17
User opened query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:34:13
DataPoint Verified.		01 Dec 2020 20:40:32
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:47
User closed query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' (Site from Safety).		30 Dec 2020 15:39:45
Query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' answered with 'data entry error, now corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:56:10
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:55:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	29 Dec 2020 17:55:17
User opened query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure answer should be Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:34:27
DataPoint Verified.		01 Dec 2020 20:40:37
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:41:25
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '0'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:56:32
User closed query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #10 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).		21 Dec 2020 08:47:04
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #10 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' answered with 'corrected per query' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:13:04
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:12:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:12:08
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #10 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:11:59
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #3 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' canceled (Site from DM).		04 Dec 2020 10:11:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #3 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:11:37
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:41:27
User entered 'Fatal (FATAL)'	Tina Rountree (b) (4)	29 Nov 2020 18:15:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:30
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:41:30
User entered 'subject arrived at hospital with low platelets. Platelets would improve with transfusions but ultimately subject never recovered and bled out.'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:15:57

US3912024

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:15:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
Reviewed for Safety.		30 Nov 2020 19:33:49
User entered 'USA-US211-2020-mRNA-1273-P301000006'		30 Nov 2020 19:29:32

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:28:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:28:38
Data point term sent to Coder	System	29 Nov 2020 18:27:05
User entered 'Anemia'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'PV Query: Nulecit was administered for anemia on 12Nov2020. However, anemia was reported with event start date of 15Nov2020. Please review dates and reconcile accordingly.' (Site from Safety).		08 Apr 2021 16:34:51
Query 'PV Query: Nulecit was administered for anemia on 12Nov2020. However, anemia was reported with event start date of 15Nov2020. Please review dates and reconcile accordingly.' answered with 'dates are correct as this information was collected from medical records' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	07 Apr 2021 16:23:26
User opened query 'PV Query: Nulecit was administered for anemia on 12Nov2020. However, anemia was reported with event start date of 15Nov2020. Please review dates and reconcile accordingly.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:05
User entered '15 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:42:59
DataPoint Un-verified.	Sandra Clancy (b) (4)	18 Dec 2020 21:14:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:14:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:42:57
User closed query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' (Site from CRA). Query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' answered with 'corrected' (Site from CRA). DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4) (b) (4) Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:42:55 18 Dec 2020 21:14:17 18 Dec 2020 21:14:02 18 Dec 2020 21:14:02
User entered empty; reason for change Data Entry Error User opened query ' Per eCRF guidelines v2.0, Page 38: All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank' (Site from CRA). Query 'Per eCRF guidelines v2.0, Page 38: Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. ' canceled (Site from CRA). DataPoint Verified.	Sandra Clancy (b) (4) (b) (4) (b) (4), (b) (6)	09 Dec 2020 17:48:08 09 Dec 2020 17:47:55 01 Dec 2020 20:44:06
User opened query 'Per eCRF guidelines v2.0, Page 38: Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. ' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:43:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	01 Dec 2020 10:12:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'subject never recovered from anemia prior to death. ' (Site from System).	Tina Rountree (b) (4)	29 Nov 2020 18:28:41
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	29 Nov 2020 18:26:45
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '3 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '22 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:55
User closed query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).		30 Dec 2020 17:15:20
Query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' answered with 'entry corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:15:53
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:15:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:15:29
User opened query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:32:21
DataPoint Verified.		01 Dec 2020 20:44:25
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:13:57
User closed query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' (Site from Safety).		30 Dec 2020 17:15:22
Query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' answered with 'entry error now corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:16:10
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:15:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:15:29
User opened query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure answer should be Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:32:03
DataPoint Verified.		01 Dec 2020 20:44:25
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		13 Apr 2021 09:37:43
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'see line 41 con med log' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Apr 2021 15:31:18
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:53:24
DataPoint Verified.		30 Mar 2021 15:41:38
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	30 Mar 2021 13:43:42
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:59:28
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:59:28
User entered '1' reason for change: Per Query Resolution	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:59:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered '1'	Tina Rountree (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:14:12
DataPoint Un-verified.	Sandra Clancy (b) (4)	23 Dec 2020 20:30:46
User entered 'ANEMIA NOTED IN MEDICAL RECORDS. SUBJECT REMAINED ANEMIC UNTIL DEATH.	(b) (4) Sandra Clancy (b) (4)	23 Dec 2020 20:30:46
Hgb on admission 12.6 & stable. On 08Nov Hgb dropped to 10.9, with post-op was 8.7 on 09Nov. On 15Nov Hgb dropped to 6.2; PRBC were given; on 17Nov Hgb 7.8 and Hct 23.7 with platelet count of 31k.' reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:20
User entered 'Anemia noted in medical records. Subject remained anemic until death.'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (11)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:26:45

US3912024

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	29 Nov 2020 18:26:45

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
Reviewed for Safety.		30 Nov 2020 19:35:19
User entered 'USA-US211-2020-mRNA-1273-P301000006'		30 Nov 2020 19:35:05

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:03:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:03:03
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:43:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 18:43:11
Data point term sent to Coder	System	29 Nov 2020 18:42:06
User entered 'acute hypoxic respiratory failure'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '20 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:53:48
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	21 Dec 2020 15:59:24
DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4)	21 Dec 2020 15:53:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	21 Dec 2020 15:53:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:53:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Dec 2020 15:59:24
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	21 Dec 2020 15:59:24
User entered '22 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	21 Dec 2020 15:59:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Dec 2020 15:53:47
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Dec 2020 15:53:47
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	21 Dec 2020 15:53:47
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '22 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'Grade 4 (Grade 4)'	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Nov 2020 18:41:41
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Nov 2020 18:41:41
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Nov 2020 18:41:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	29 Nov 2020 18:41:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '22 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	29 Nov 2020 18:41:41
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	29 Nov 2020 18:41:41
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	29 Nov 2020 18:41:25
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

US3912024

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:14:26
User closed query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).		30 Dec 2020 17:18:24
Query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' answered with 'entry error now corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:04
User opened query 'PV Query: As the subject has received study drug the causality assessment should be 'Related' or 'Not related'. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:30:00
DataPoint Verified.		01 Dec 2020 20:44:23
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:14:28
User closed query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' (Site from Safety).		30 Dec 2020 17:18:26
Query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' answered with 'entry error now corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:28
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:17:04
User opened query 'PV Query: Please provide the rationale why the events were assessed as Not applicable to study procedure. Since the subject did receive study drug and went through study procedure, answer should be Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:31:44
DataPoint Verified.		01 Dec 2020 20:44:23
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #7 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:43:22
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #7 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' answered with 'both events had the same result of being fatal; the subject's health situation was dire and as all systems began to fail, the last event noted here, acute respiratory failure, would be the final episode resulting in death.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:22:56
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #7 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:44:24
User closed query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #3 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).		28 Dec 2020 17:26:19

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[Outcome](#)

Audit	User	Time (GMT)
Query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE #3 outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' answered with 'this entry is correct' (Site from DM).	Sandra Clancy (b) (4)	21 Dec 2020 15:54:43
User opened query 'Per CDM : Per CCG, Page 39, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. AE # outcome is recorded as FATAL. Please update appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:13:41
DataPoint Verified.		01 Dec 2020 20:44:23
User entered 'Fatal (FATAL)'	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:25

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
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 are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:18:29
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 are sent or, if unable to obtain, please state so.' answered with 'sending today' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:23:40
Query 'IQVIA medical query: Please provide the rationale why the events were assessed as Not applicable to study procedure.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:39:15
User closed query '(4,5,7, 8, 9, 10, 11, 12) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).		28 Dec 2020 18:39:01
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 are sent or, if unable to obtain, please state so.' (Site from Safety).		28 Dec 2020 18:31:01
Query '(4,5,7, 8, 9, 10, 11, 12) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' answered with 'please find additional information in the narratives of the above events. if there are questions, please provide the query in the corresponding event. thank you' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 16:32:11
User closed query 'PV Query: Please remove the end date for events ongoing at the time of death.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 16:14:51

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EAB) (1725)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please remove the end date for events ongoing at the time of death.' answered with 'corrected' (Site from Safety).	Sandra Clancy (b) (4)	21 Dec 2020 15:54:59
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:18:14
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Per the family, there wasn't an autopsy planned.' (Site from Safety).	Sandra Clancy (b) (4)	18 Dec 2020 21:23:58
User opened query 'IQVIA medical query: Please provide the rationale why the events were assessed as Not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:18:29
User opened query 'PV Query: Please remove the end date for events ongoing at the time of death.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:17:45
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:16:06
User opened query '(4,5,7, 8, 9, 10, 11, 12) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:13:06
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:44:23
User entered 'subject went into acute hypoxic respiratory failure which resulted in subject being intubated and moved to ICU. Subjects family then decided to discontinue any life saving measures. Subject was taken off of ventilator on 22NOV2020'	Tina Rountree (b) (4)	29 Nov 2020 18:41:25

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:41:25

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Folder: Adverse Events

Form: Adverse Events (12)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Nov 2020 18:41:25

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:31:21
Un-reviewed for Safety.		26 Jan 2021 13:09:10
User entered empty; reason for change New Information		26 Jan 2021 13:09:10
Reviewed for Safety.		22 Jan 2021 12:16:40
User entered 'USA-US211-2020-mRNA-1273-P301000006'		22 Jan 2021 12:16:37

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'For coding purposes, please split BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING into separate entries. ' (Site from Coder).		22 Mar 2021 13:15:16
User closed query 'Per DM CLR-RQ: In reference to previous query. Please remove the term "worsening" if no baseline MH or previous AE that preludes this condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		15 Mar 2021 18:46:50
Query 'Per DM CLR-RQ: In reference to previous query. Please remove the term "worsening" if no baseline MH or previous AE that preludes this condition. Update as appropriate. Otherwise, provide clarification.' answered with 'see AE log line #21' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 15:57:26
User opened query 'Per DM CLR-RQ: In reference to previous query. Please remove the term "worsening" if no baseline MH or previous AE that preludes this condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 04:45:59
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:19:40
DataPoint Un-verified.		03 Mar 2021 15:19:38
User closed query 'PER DM CLR: RQ: Response noted. However, BIBASAL INFILTRATES, PLEURAL EFFUSIONS is not even recorded as AE, however it is recorded as worsening. Kindly consider review and update as appropriate. Thank you.' (Site from DM).		26 Feb 2021 13:13:39
Query 'PER DM CLR: RQ: Response noted. However, BIBASAL INFILTRATES, PLEURAL EFFUSIONS is not even recorded as AE, however it is recorded as worsening. Kindly consider review and update as appropriate. Thank you.' answered with 'AE prepared as requested' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:41:06

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Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PER DM CLR: RQ: Response noted. However, BIBASAL INFILTRATES, PLEURAL EFFUSIONS is not even recorded as AE, however it is recorded as worsening. Kindly consider review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:02:41
User closed query 'Per DM CLR: Please confirm the AE term "BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).		23 Feb 2021 13:02:41
Query 'Per DM CLR: Please confirm the AE term "BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'The subject was noted to have a change in lung function/appearance according to the CT performed on 08Nov2020. Atelectasis was noted on this date but as hospitalization continued, condition did worsen and this was noted as an event for that reason. On 13Nov2020 CT revealed	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:15:31
"increasing severity bibasal atelectasis and infiltrates, increasing volume small to moderate bilateral pleural effusions."		
It is not part of medical history; the wording for the event it taken verbatim from medical records.' (Site from DM).		

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm the AE term "BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:31:26
Query 'For coding purposes, please split BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING into separate entries. ' answered with 'This description is directly from medical records - will leave as is.' (Site from Coder).	Sandra Clancy (b) (4)	10 Feb 2021 17:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:31:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4)	02 Feb 2021 13:41:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Feb 2021 13:41:27
User opened query 'For coding purposes, please split BIBASAL INFILTRATES, PLEURAL EFFUSIONS, WORSENING into separate entries. ' (Site from Coder).	(b) (4), (b) (6)	02 Feb 2021 13:40:58
Data point term sent to Coder	System	21 Jan 2021 17:24:28
User entered 'bibasal infiltrates, pleural effusions, worsening'	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:31:30
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:31:33
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '18 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 17:24:17

US3912024

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:45:47
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 19:45:47
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	25 Jan 2021 19:45:47
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:45:47
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	21 Jan 2021 17:24:17
User entered '22 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:56:29
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		25 Jan 2021 19:57:25
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		25 Jan 2021 19:57:25
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	25 Jan 2021 19:56:29
User closed query 'Requires inpatient or prolongation System 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).		25 Jan 2021 19:56:29
Query 'Requires inpatient or prolongation of existing System 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).		25 Jan 2021 19:56:29
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:56:29
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).	(b) (4) System	21 Jan 2021 17:24:17
User entered '1'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:57:02
User entered '3 Nov 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:57:25
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	25 Jan 2021 19:48:37
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).		25 Jan 2021 19:48:37
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:48:37
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	21 Jan 2021 17:24:17
User entered 'Unknown (UNK)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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Folder: Adverse Events

Form: Adverse Events (13)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).		15 Mar 2021 18:47:02
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'correct per medical records' (Site from DM).	Sandra Clancy (b) (4)	12 Mar 2021 15:57:52
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 04:46:27
DataPoint Verified.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 15:19:52
User entered '1' reason for change: Data Entry Error	System	22 Feb 2021 22:20:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Sandra Clancy (b) (4)	22 Feb 2021 22:20:26
DataPoint Verified.	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	22 Feb 2021 22:20:26
	(b) (4)	
	System	22 Feb 2021 22:18:51
	(b) (4), (b) (6)	02 Feb 2021 16:32:10
	(b) (4)	
	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:19:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		23 Feb 2021 09:28:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:20:37
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:18:51
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:18:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:31:16
DataPoint Verified.		02 Feb 2021 16:32:10
User entered '1'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered '0'	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:32:10
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 17:24:17

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:32:10
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 19:56:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 19:56:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 17:24:17
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:24:17

US3912024

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	25 Jan 2021 19:56:29
User entered '1'	System	21 Jan 2021 17:24:17

US3912024

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	21 Jan 2021 17:24:17

US3912024

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	21 Jan 2021 17:24:17

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Atelectasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:45:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:45:08
Data point term sent to Coder	System	21 Jan 2021 22:25:35
User entered 'Atelectasis bilateral lower lobes'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '5 Nov 2020'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	21 Jan 2021 22:25:15

US3912024

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '1'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	21 Jan 2021 22:25:15

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
Un-reviewed for Safety.		26 Jan 2021 13:08:25
User entered empty; reason for change Per Query Resolution		26 Jan 2021 13:08:25
Reviewed for Safety.		22 Jan 2021 12:18:37
User entered 'USA-US211-2020-mRNA-1273-P301000006'		22 Jan 2021 12:18:34

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	30 Mar 2021 15:38:21
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:00
User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4), (b) (6)	23 Mar 2021 08:13:20
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Malnutrition, LLT: Malnutrition - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 16:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	22 Mar 2021 16:35:46
Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	Sandra Clancy (b) (4)	22 Mar 2021 16:35:44
' answered with 'event corrected per query' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 16:34:29
DataPoint Un-verified.	Sandra Clancy (b) (4)	22 Mar 2021 16:34:07
Coding entries removed.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 16:34:07
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 16:34:07
User entered 'MALNUTRITION' reason for change:	(b) (4)	
Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 16:34:07
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4), (b) (6)	19 Mar 2021 06:12:27
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 15:18:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Malnutrition, LLT: Malnutrition - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 00:48:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 00:48:12
	(b) (4)	
Data point term sent to Coder	System	23 Feb 2021 15:01:09
DataPoint Un-verified.	Sandra Clancy (b) (4)	23 Feb 2021 15:00:32
	(b) (4)	
Coding entries removed.	Sandra Clancy (b) (4)	23 Feb 2021 15:00:32
	(b) (4)	
User entered 'MALNUTRITION, worsening' reason for change: Data Entry Error	Sandra Clancy (b) (4)	23 Feb 2021 15:00:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Malnutrition, LLT: Malnutrition - version MedDRA\23.0.	Coder Import (b) (4)	21 Jan 2021 22:38:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Jan 2021 22:38:08
	(b) (4)	
Data point term sent to Coder	System	21 Jan 2021 22:37:40
User entered 'Malnutrition'	Tina Rountree (b) (4)	21 Jan 2021 22:36:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Yes (Y)'	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '20 Nov 2020'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: This condition has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment. ' (Site from DM).		06 Apr 2021 11:47:41
Query 'Per DM CLR: This condition has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment. ' answered with 'Per eCRF Guidelines v5.0, "AEs that are ongoing at the time of death should not have an end date." Subject passed away on 22-Nov-2020. This AE will be left without an end date as this did not have a fatal outcome. ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:25:48
User opened query 'Per DM CLR: This condition has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 03:07:48
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).		26 Jan 2021 13:07:48
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'confirmed it is not SAE' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:57:41
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 22:57:23
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:57:23
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:13:41
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Jan 2021 22:36:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

US3912024

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	22 Feb 2021 22:25:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Feb 2021 22:25:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:36:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:20
User closed query 'PER DM CLR: RQ: Per response it was reported as 'correct as it'. However, concomitant medication start date is prior to AE start date. Please review and reconcile and update as appropriate. Thank you.' (Site from DM).		26 Feb 2021 13:13:54
Query 'PER DM CLR: RQ: Per response it was reported as 'correct as it'. However, concomitant medication start date is prior to AE start date. Please review and reconcile and update as appropriate. Thank you.' answered with 'Due to the severity of the subject's overall condition he was given TPN prior to the notation of malnutrition; however, the actual issue of malnutrition being noted and addressed in the records did not appear until the start date as noted here for this event.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 15:05:59
User opened query 'PER DM CLR: RQ: Per response it was reported as 'correct as it'. However, concomitant medication start date is prior to AE start date. Please review and reconcile and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:17:48
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #31 recorded that machth this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).		23 Feb 2021 13:17:48
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:25:40
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:25:40

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #31 recorded that mach this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'correct as is' (Site from DM).	Sandra Clancy (b) (4)	22 Feb 2021 22:21:39
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #31 recorded that mach this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:31:50
DataPoint Verified.		02 Feb 2021 16:33:44
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4)	23 Feb 2021 13:03:54
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:25:23
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:25:01
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:25:01
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:31:40
	(b) (4)	02 Feb 2021 16:33:44
User entered '1'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 22:57:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 22:57:23
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 22:36:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	25 Jan 2021 22:57:23
User entered '1'	System	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:19:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	21 Jan 2021 22:36:43

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Folder: Adverse Events

Form: Adverse Events (16)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

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Folder: Adverse Events

Form: Adverse Events (17)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial pyelonephritis, LLT: Bacterial pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:30:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:30:03
Data point term sent to Coder	System	21 Jan 2021 22:42:46
User entered 'Klebsiella Complicated Pyelonephritis'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Yes (Y)'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '17 Nov 2020'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '1'	Tina Rountree (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered '0'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:33:50
User entered empty.	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	21 Jan 2021 22:41:52

US3912024

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:59
User entered 'USA-US211-2020-mRNA-1273-P301000006'		23 Feb 2021 14:25:52

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	15 Mar 2021 18:50:17
User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:43:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Generalised oedema, LLT: Anasarca - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:59:48
Data point term sent to Coder	System	12 Mar 2021 15:59:09
Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 15:58:44
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 15:58:36
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 15:58:36
User entered 'ANASARCA' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 15:58:36
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 04:41:58

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:16:58
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Generalised oedema, LLT: Anasarca - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:26:09
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 11:26:09
Data point term sent to Coder	System	25 Jan 2021 19:30:54
User entered 'anasarca, worsening'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:00
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:04
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:06
User entered 'No (N)'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:08
User entered '8 Nov 2020'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:10
User entered empty.	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
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).		30 Mar 2021 13:12:23
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 'per DM directive, an end date was not to be provided for these events (under the SAE) unless the event was the cause of death. please clarify.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:32:03
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)	28 Mar 2021 22:33:36
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:20
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:22
User entered empty.	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:24
User entered empty.	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:28
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:31
User entered '0'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:33
User entered '0'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:35
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	25 Jan 2021 19:31:23
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	25 Jan 2021 19:31:23
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	25 Jan 2021 19:30:38
User entered '1'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:37
User entered '3 Nov 2020'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:39
User entered '22 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:31:23
User entered empty.	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:40
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:46
User entered empty.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:59
User entered '0'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:57
User entered '0'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:55
User entered '0'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:48
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:17:50
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:17:54
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	30 Mar 2021 15:37:52
User signature succeeded.	Mark Hutchens (b) (4)	30 Mar 2021 13:43:42
User closed query 'Per DM CLR: Other Action Taken = None. However, please verify if the procedure of CT GUIDED DRAIN PLACEMENT was performed for this AE. IF yes, please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:12:32
Query 'Per DM CLR: Other Action Taken = None. However, please verify if the procedure of CT GUIDED DRAIN PLACEMENT was performed for this AE. IF yes, please review and update AE eCRF as appropriate.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4)	29 Mar 2021 23:34:13
DataPoint Un-verified.	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
Signature has been broken.	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
User opened query 'Per DM CLR: Other Action Taken = None. However, please verify if the procedure of CT GUIDED DRAIN PLACEMENT was performed for this AE. IF yes, please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 22:33:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4)	15 Mar 2021 18:44:11
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'correct per medical records' (Site from DM).	Sandra Clancy (b) (4)	12 Mar 2021 15:59:00

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	12 Mar 2021 04:42:17
DataPoint Verified.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	(b) (4), (b) (6) System	03 Mar 2021 15:22:58
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:37:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	Sandra Clancy (b) (4) System	22 Feb 2021 22:37:36
User entered '0'	(b) (4), (b) (6) (b) (4)	22 Feb 2021 22:37:18
	(b) (4), (b) (6) (b) (4)	02 Feb 2021 16:18:01
	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per source documentation, concomitant medication was taken for anasarca. Please update and clarify which medication was taken for anasarca, or clarify source documentation. ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 12:57:16
Query 'Per source documentation, concomitant medication was taken for anasarca. Please update and clarify which medication was taken for anasarca, or clarify source documentation. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:06:44
User opened query 'Per source documentation, concomitant medication was taken for anasarca. Please update and clarify which medication was taken for anasarca, or clarify source documentation. ' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 15:40:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:03
User entered '0'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	30 Mar 2021 15:37:59
User signature succeeded.	Mark Hutchens (b) (4)	30 Mar 2021 13:43:42
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	29 Mar 2021 23:33:15
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 15:19:03
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.		23 Feb 2021 13:18:25
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.	Sandra Clancy (b) (4)	22 Feb 2021 22:37:45
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Sandra Clancy (b) (4)	22 Feb 2021 22:37:18
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Feb 2021 22:37:18
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.	(b) (4), (b) (6)	20 Feb 2021 01:32:03
' (Site from DM).		
DataPoint Verified.		02 Feb 2021 16:18:05

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:09
User entered empty.	Sandra Clancy (b) (4)	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:11
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 19:42:21
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 19:42:21
User entered 'On 08Nov2020 the subject underwent an exploratory laparotomy for what was suspected to be a bowel perforation; however, once the procedure was underway, it was not a bowel perforation but duodenal ulcer, which was further complicated by significant adhesions and multiple loculated fluid collections. A CT performed on 13Nov2020 indicated worsening soft tissue anasarca. As late as 19Nov2020 the subject again developed collection of fluid throughout the peritoneal cavity, largest of which extended from the left upper quadrant caudally into the pelvis.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:42:21
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 19:30:38
User entered empty.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	25 Jan 2021 19:30:38

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:34:34
Reviewed for Safety.		29 Jan 2021 20:50:02
User entered 'USA-US211-2020-mRNA-1273-P301000006'		29 Jan 2021 20:49:56

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:34:37
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 21:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 21:18:23
Data point term sent to Coder	System	28 Jan 2021 21:17:28
User entered 'GI Bleed'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'No (N)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'No (N)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '8 Nov 2020'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:23
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 17:12:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 17:12:26
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 17:12:26
DataPoint Verified.	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 21:17:06
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 17:14:41
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	10 Feb 2021 17:14:41
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	10 Feb 2021 17:12:26
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
User entered '22 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'PV Query: Please provide the event end date if the GI bleed resolved prior to the death if remained ongoing at the time of death please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:56:11
Query 'PV Query: Please provide the event end date if the GI bleed resolved prior to the death if remained ongoing at the time of death please state so.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4)	10 Feb 2021 17:15:05
User opened query 'PV Query: Please provide the event end date if the GI bleed resolved prior to the death if remained ongoing at the time of death please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:33:53
DataPoint Verified.	(b) (4)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:42:35
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
User entered 'Grade 4 (Grade 4)' reason for change:	(b) (4)	
Data Entry Error	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:55:41
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4)	10 Feb 2021 17:15:14
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 17:12:26
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).		29 Jan 2021 20:49:12
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Jan 2021 21:17:06
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:42:37
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
User entered '1' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	10 Feb 2021 17:12:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:23:06
User closed query 'Per DM CLR: Other Action Taken = None, however there were ConProc #2 and 3 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		23 Feb 2021 13:18:47
Query 'Per DM CLR: Other Action Taken = None, however there were ConProc #2 and 3 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:40:38
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:40:18
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Feb 2021 22:40:18
User opened query 'Per DM CLR: Other Action Taken = None, however there were ConProc #2 and recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:32:15
DataPoint Verified.		02 Feb 2021 16:35:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Jan 2021 21:17:34
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:34
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Jan 2021 21:17:06
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:23:08
DataPoint Un-verified.	Sandra Clancy (b) (4)	22 Feb 2021 22:40:18
User entered '1' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	22 Feb 2021 22:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:42:41
User closed query 'PV Query: Please provide the final event outcome for the event. If the GI bleed did not resolve prior to the death, please update the outcome.' (Site from Safety).		11 Feb 2021 16:55:57
Query 'PV Query: Please provide the final event outcome for the event. If the GI bleed did not resolve prior to the death, please update the outcome.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:15:28
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:14:41
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:14:41
User opened query 'PV Query: Please provide the final event outcome for the event. If the GI bleed did not resolve prior to the death, please update the outcome.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:34:09
DataPoint Verified.		02 Feb 2021 16:35:25
User entered 'Unknown (UNKNOWN)'	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:35:25
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 21:17:06

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Narrative = BLOOD IN THE URINE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4)	30 Mar 2021 13:13:21
Query 'Per DM CLR: Narrative = BLOOD IN THE URINE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'this is part of the bleed - not a separate issue/AE' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:38:06
User opened query 'Per DM CLR: Narrative = BLOOD IN THE URINE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 22:33:51
DataPoint Verified.	(b) (4)	15 Mar 2021 15:41:14
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per CDM: Please provide the missing date appropriately.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:59:57

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'AT THE SUBJECT'S INITIAL PRESENTATION TO THE ER ON 03NOV2020, THERE WERE A HOST OF MEDICAL ISSUES THAT APPEARED TO CASCADE ONCE OBSTRUCTING NEPHROLITHIASIS WAS ADDRESSED WITH URETERAL STENT PLACEMENT. THE SUBJECT'S CONDITION WAS COMPLICATED BY THROMBOCYTOPENIA, A DECLINE IN HEMOGLOBIN DESPITE SEVERAL TREATMENTS WITH BLOOD PRODUCTS. ALTHOUGH THE RECORDS INDICATE THAT MONITORING FOR ONGOING BLEEDING WAS TO CONTINUE, THE SUBJECT DOES NOT APPEAR TO STABLIZE; ON 20NOV2020, IT WAS NOTED THAT THERE IS BLOOD IN THE URINE; LATER THAT SAME DAY, THE SUBJECT CODED. DURING RESCUE MEASURES, IT WAS NOTED THAT THE SUBJECT HAD ACTIVE BLEEDING IN THE BACK OF HIS MOUTH, AS WELL AS THE PRESENCE OF DRIED BLOOD. Throughout the records it appears that there may have been a strong suspicion for post-op bleeding; efforts to recover from decreasing platelets and down-trending hemoglobin were unsuccessful. On 20Nov2020, the following lab results were noted: RBC=1.98; HGB=6.0; HCT=19.9; PLTS=49.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 18:47:31
Query 'Per CDM: Please provide the missing date appropriately.' answered with 'all dates entered' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 18:35:39
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Mar 2021 18:34:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	08 Mar 2021 18:34:55
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 18:34:55

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (19)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'At the subject's initial presentation to the ER on 03Nov2020, there were a host of medical issues that appeared to cascade once obstructing nephrolithiasis was addressed with ureteral stent placement. The subject's condition was complicated by thrombocytopenia, a decline in hemoglobin despite several treatments with blood products. Although the records indicate that monitoring for ongoing bleeding was to continue, the subject does not appear to stabilize; on 20Nov2020, it was noted that there is blood in the urine; later that same day, the subject coded. During rescue measures, it was noted that the subject had active bleeding in the back of his mouth, as well as the presence of dried blood.'	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 18:34:55
reason for change: Data Entry Error		
User opened query 'Per CDM: Please provide the missing date appropriately.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:48:31
DataPoint Verified.		02 Feb 2021 16:35:25
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 21:17:06
User entered empty.	Tina Rountree (b) (4) (b) (4)	28 Jan 2021 21:17:06

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	28 Jan 2021 21:17:06

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	28 Jan 2021 21:17:06

US3912024

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
Reviewed for Safety.		23 Feb 2021 14:27:21
User entered 'USA-US211-2020-mRNA-1273-P301000006'		11 Feb 2021 17:38:34

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	7 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).		5 Mar 2021 18:49:01
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'see narrative below - this information has been taken directly from medical records which have been provided to the Safety group - no changes to this event.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Mar 2021 16:00:49
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 04:47:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:53
User coded data point as SOC: Gastrointestinal disorders, HLG: Peritoneal and retroperitoneal conditions, HLT: Peritoneal and retroperitoneal disorders, PT: Intra-abdominal fluid collection, LLT: Intra-abdominal fluid collection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:46:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:46:47
Data point term sent to Coder	System	10 Feb 2021 17:24:20
User entered 'intraabdominal fluid'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '8 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered empty.	Sandra Clancy (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
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	23 Feb 2021 00:37:44
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	23 Feb 2021 00:37:44
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	10 Feb 2021 17:23:54
User entered '1'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '3 Nov 2020'	Sandra Clancy (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '22 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	23 Feb 2021 00:37:44
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered '1'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:53
User entered empty.	Sandra Clancy (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Feb 2021 15:44:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Feb 2021 15:44:37
User entered 'Post surgery for ureteral stent placement, it was noted on renal ultrasound dated 06Nov2020 that there was small volume ascites; it is noted on 08Nov2020 that subject had worsening of lower abdominal pain, more constant and severe, with decrease appetite and nausea. A CT on 08Nov2020 revealed "moderately large volume of intraabdominal free fluid, with large amount of pneumoperitoneum." The subject was taken to the OR on 08Nov2020 where he underwent closure of perforated duodenal ulcer, extensive lysis of adhesions and drainage of peritoneal abscesses. The peritoneal cavity total fluid that was removed was about 1400mL of purulent fluid. Subsequently a JP drain was placed in the right upper quadrant prior to leaving the OR. On 13Nov2020 CT performed of the abdomen/pelvis revealed findings of residual ascites in the pelvis and small loculations of fluid adjacent to the descending colon. Abdominal pain continues through 17Nov2020, with "yellow liquid from around the JP drain site that is drenching the bed". A CT was performed on 19Nov2020 revealing "diffuse water density, simple appearing loculated collection of fluid throughout the peritoneal cavity, largest of which extends from the left upper quadrant caudally into the pelvis". On 20Nov2020 subject underwent CT-guided drainage as opposed to draining through the drain.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 15:44:37

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Feb 2021 17:23:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	10 Feb 2021 17:23:54

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Lung infiltration, LLT: Bilateral pulmonary infiltrates - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 06:28:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 06:28:13
Data point term sent to Coder	System	23 Feb 2021 14:58:06
User entered 'bibasal infiltrates'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '8 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

US3912024

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 23:38:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 23:38:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 23:38:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 14:57:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 23:38:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 23:38:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 23:38:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 14:57:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'None (NONE)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '1'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:44:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '0'	System	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	23 Feb 2021 14:57:40

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:19:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:07:46
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:47:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:19:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:43:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:43:19
Data point term sent to Coder	System	21 Jan 2021 00:42:39
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:41:45
Coding entries removed.	(b) (4) Sandra Clancy (b) (4)	21 Jan 2021 00:41:45
User entered 'HYDrOXyZINE' reason for change:	(b) (4) Sandra Clancy (b) (4)	21 Jan 2021 00:41:45
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:59:48
Data point term sent to Coder	System	29 Aug 2020 21:51:33
Data point term sent to Coder	System	29 Aug 2020 21:48:31
User entered 'Hydoxidine'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'Anxiety' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered '10' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'mg (mg)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'as needed (PRN)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Aug 2020 21:51:01
User entered 'un UNK 2012' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 21:51:01
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:48:15
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:48:15

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
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)	21 Jan 2021 00:43:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 00:43:19
Data point term sent to Coder	System	21 Jan 2021 00:42:40
Coding entries removed.	Sandra Clancy (b) (4)	21 Jan 2021 00:42:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:48
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)	29 Aug 2020 21:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 21:53:46
Data point term sent to Coder	System	29 Aug 2020 21:52:34
User entered 'Tamsulosin'	Tina Rountree (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:19:41
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:42:23
User entered 'benign prostatic hyperplasia' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	21 Jan 2021 00:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'Overactive Bladder'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered '0.4'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'un UNK 2016'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 22:00:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 22:00:37
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:37
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:52:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	29 Aug 2020 21:52:05

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:44:42
Data point term sent to Coder	System	29 Aug 2020 21:54:36
User entered 'Voltaren 1%'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Please update CM indication to include the specific location of the ARTHRITIS PAIN (i.e.: Right, Left, Bilateral knees, hips etc.). Update CM page, and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:04:26
Query 'Per DM CLR: Please update CM indication to include the specific location of the ARTHRITIS PAIN (i.e.: Right, Left, Bilateral knees, hips etc.). Update CM page, and ensure to reconcile with the MH page so there is a match as appropriate. ' answered with 'unknown location. LM for subject to call back so we can clarify location. ' (Site from DM)		11 Nov 2020 00:29:41
User opened query 'Per DM CLR: Please update CM indication to include the specific location of the ARTHRITIS PAIN (i.e.: Right, Left, Bilateral knees, hips etc.). Update CM page, and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).		10 Nov 2020 19:52:47
Query 'Per DM CLR: Please review the indication to include the specific location of ARTHRITIS PAIN (e.g. Back, Generalized, Left Knee, etc.). Reconcile and update as appropriate.' canceled (Site from DM).		30 Sep 2020 12:57:02
User opened query 'Per DM CLR: Please review the indication to include the specific location of ARTHRITIS PAIN (e.g. Back, Generalized, Left Knee, etc.). Reconcile and update as appropriate.' (Site from DM).		20 Sep 2020 15:56:43
DataPoint Verified.		16 Sep 2020 18:08:56
User entered 'Arthritis Pain'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'Other (OTHER)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'Application'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'Topical (TOPICAL)'	Tina Rountree (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'un UNK 2012'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered '0'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:08:56
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:54:35

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE, PRODUCTSYNONYM: PRESERVISION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:24:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:24:55
Data point term sent to Coder	System	29 Aug 2020 21:56:38
User entered 'Preservision'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Vision Loss'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Other (OTHER)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Soft Gel'	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'un Aug 2019'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:05
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:05
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 22:00:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 22:00:58
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:58
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:55:58
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:55:58

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN;GUAIFENESIN, PRODUCTSYNONYM: MUCUS RELIEF DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 21:58:47
Data point term sent to Coder	System	29 Aug 2020 21:57:40
User entered 'Mucus Relief DM'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'Seasonal Allergies'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:50:47
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' (Site from DM).		08 Oct 2020 06:50:23
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' answered with 'confirmed and updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:48:11
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:47:53
User entered '400/20' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:47:53
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:57:18
DataPoint Verified.		16 Sep 2020 18:09:12
User entered '1'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:50:53
DataPoint Un-verified.	Tina Rountree (b) (4)	03 Oct 2020 15:47:53
User entered 'mg (mg)' reason for change: Data Entry Error	Tina Rountree (b) (4)	03 Oct 2020 15:47:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'tablet (TABLET)'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'as needed (PRN)'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'un UNK 2017'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 22:01:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 22:01:15
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	29 Aug 2020 22:01:15
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 21:56:55
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 21:56:55

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:25:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:25:45
Data point term sent to Coder	System	29 Aug 2020 22:00:45
User entered 'Allergy Relief - Levocetirizine Dihydrochloride'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'No (N)'	Tina Rountree (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'Seasonal Allergies'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered '5'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered '01 Jul 2020'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered '0'	Tina Rountree (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered empty.	Tina Rountree (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:21
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	29 Aug 2020 22:00:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:02:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:02:54
Data point term sent to Coder	System	05 Sep 2020 01:21:21
User entered 'neilmed nasal mist (saline)'	(b) (4), (b) (6)	05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'No (N)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'seasonal allergies'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered '1'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'Other (OTHER)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'spray'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'as needed (PRN)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered empty.		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'Nasal (NASAL)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered empty.		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered '02 Sep 2020'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered '0'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'Yes (Y)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered empty.		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:09:27
User entered 'No (N)'		05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	05 Sep 2020 01:21:13

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 15:52:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 15:52:38
Data point term sent to Coder	System	18 Dec 2020 15:45:29
User entered 'influzena vaccine'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'flu prevention'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
Query 'Per CDM: Requery: Response noted. however dose unit cannot be 'Injection'. If dose unit in unknown consider updating 'Unknown' else update as appropriate. Thank you.' canceled (Site from DM).		29 Dec 2020 11:56:38
User opened query 'Per CDM: Requery: Response noted. however dose unit cannot be 'Injection'. If dose unit in unknown consider updating 'Unknown' else update as appropriate. Thank you.' (Site from DM).		29 Dec 2020 08:28:24
User closed query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'Injection'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).		29 Dec 2020 08:28:24
Query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'Injection'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' answered with 'exact dose is not available and there are no source records to provide further details, ergo, this is the reason it is listed this way.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:32:02
User opened query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'Injection'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:25:37
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'injection'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once (ONCE)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intramuscular (INTRAMUSCULAR)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '23 Oct 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '23 Oct 2020'	Sandra Clancy (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:44:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Jan 2021 22:13:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 22:13:08
Data point term sent to Coder	System	20 Jan 2021 22:12:06
Coding entries removed.	Sandra Clancy (b) (4)	20 Jan 2021 22:11:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 15:48:48
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 Dec 2020 15:48:48
Data point term sent to Coder	System	18 Dec 2020 15:47:30
User entered 'dilaudid'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:36:05
User closed query 'Per DM CLR: For CM Line #s 9,12,19 & 24: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		29 Jan 2021 09:59:42
Query 'Per DM CLR: For CM Line #s 9,12,19 & 24: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:11:45
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:11:35
User entered 'obstructing nephrolithiasis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:11:35
User opened query 'Per DM CLR: For CM Line #s 9,12,19 & 24: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:35:30
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'intractable renal colic'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0.5'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '3 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:46:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:46:41
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:46:30
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	18 Dec 2020 18:25:44
User entered '10 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:25:44
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	18 Dec 2020 15:46:41
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 15:46:30

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:36:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:36:40
Data point term sent to Coder	System	18 Dec 2020 18:36:02
User entered 'zosyn'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:34:59
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'see adverse events have been updated' (Site from DM).	Sandra Clancy (b) (4)	25 Jan 2021 18:53:54
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:31:13
DataPoint Verified.	(b) (4)	08 Jan 2021 22:21:27
User entered 'klebsiella complicated pyelonephritis'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4.5'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'g (g)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'three times daily (TID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '3 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '17 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '3'	System	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 18:35:57

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 07:47:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 07:47:15
Data point term sent to Coder Coding entries removed.	System	25 Jan 2021 19:04:22
	Sandra Clancy (b) (4)	25 Jan 2021 19:03:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 22:45:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 22:45:09
Data point term sent to Coder Coding entries removed.	System	20 Jan 2021 22:40:32
	Sandra Clancy (b) (4)	20 Jan 2021 22:40:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 18:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 18:38:45
Data point term sent to Coder User entered 'fentanyl'	System	18 Dec 2020 18:38:03
	Sandra Clancy (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:36:20
User closed query 'Per DM CLR: Requery: Response noted. Please check the start date and end date of the medication as it does not match with the AE start and end date. Kindly reconcile the data and update the data accordingly. Thank you.' (Site from DM).		01 Feb 2021 08:22:38
Query 'Per DM CLR: Requery: Response noted. Please check the start date and end date of the medication as it does not match with the AE start and end date. Kindly reconcile the data and update the data accordingly. Thank you.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:03:48
User entered 'multi-system organ failure' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:03:28
User opened query 'Per DM CLR: Requery: Response noted. Please check the start date and end date of the medication as it does not match with the AE start and end date. Kindly reconcile the data and update the data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:24:12
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		25 Jan 2021 18:24:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:40:33
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:40:26
User entered 'obstructing nephrolithiasis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:40:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 08:32:09
		08 Jan 2021 22:21:27
User entered 'pain management'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '50'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Per CDM: If dose unit is other, specify is recorded "MCG". However, "ug" option is available in drop down of Dose unit. Please review and update accordingly or else clarify. Thankyou.' (Site from DM).		28 Dec 2020 15:08:02
Query 'Per CDM: If dose unit is other, specify is recorded "MCG". However, "ug" option is available in drop down of Dose unit. Please review and update accordingly or else clarify. Thankyou.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:33:28
User entered 'ug (ug)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:33:14
User opened query 'Per CDM: If dose unit is other, specify is recorded "MCG". However, "ug" option is available in drop down of Dose unit. Please review and update accordingly or else clarify. Thankyou.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:27:12
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	23 Dec 2020 19:33:14
User entered 'mcg'	(b) (4) Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once (ONCE)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:37:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:43:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:43:17
Data point term sent to Coder	System	20 Jan 2021 23:27:56
Coding entries removed.	Sandra Clancy (b) (4)	20 Jan 2021 23:27:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:55:37
Data point term sent to Coder	System	18 Dec 2020 18:39:04
User entered 'oxycodone'	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:36:45
DataPoint Un-verified.	Sandra Clancy (b) (4)	20 Jan 2021 23:27:33
User entered 'obstructing nephrolithiasis' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	20 Jan 2021 23:27:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'intractable renal colic'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10'	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:38:25

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:43:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:43:37
Data point term sent to Coder	System	18 Dec 2020 18:41:05
User entered 'heparin'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'to prevent clotting'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5000'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).		28 Dec 2020 15:08:22
Query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:34:22
User entered 'IU (IU)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:34:14
User opened query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:30:27
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	23 Dec 2020 19:34:14
User entered 'units'	(b) (4) Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:36:55
User closed query 'Per DM CLR: Frequency = three times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		29 Jan 2021 12:54:08
Query 'Per DM CLR: Frequency = three times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:50:08
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:49:40
User entered 'twice daily (BID)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 22:49:40
User opened query 'Per DM CLR: Frequency = three times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:32:37
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'three times daily (TID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2'	System	20 Jan 2021 22:49:40
User entered '3'	System	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 18:40:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 11:02:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 11:02:08
Data point term sent to Coder	System	25 Jan 2021 19:05:23
Coding entries removed.	Sandra Clancy (b) (4)	25 Jan 2021 19:05:17
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:49:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:49:48
Data point term sent to Coder	System	18 Dec 2020 18:42:06
User entered 'rocephin'	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:37:08
User closed query 'Per DM CLR: For CM Line #s 14 & 21: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		29 Jan 2021 11:40:12
Query 'Per DM CLR: For CM Line #s 14 & 21: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:05:40
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:05:17
User entered 'klebsiella complicated pyelonephritis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:05:17
User opened query 'Per DM CLR: For CM Line #s 14 & 21: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:37:04
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'complicated urinary tract infection'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'g (g)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '6 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 18:41:52

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
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 BENIGN PROSTATIC HYPERTROPHY should be recorded, and update con med indication or provide clarification. ' (Site from DM).		09 Mar 2021 14:02:32
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 BENIGN PROSTATIC HYPERTROPHY should be recorded, and update con med indication or provide clarification. ' answered with 'this was a medication subject was already using - this was the dose provided during hospitalization.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 18:54:14
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 BENIGN PROSTATIC HYPERTROPHY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:39:14
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:44:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Dec 2020 18:44:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	18 Dec 2020 18:44:08
User entered 'flomax'	Sandra Clancy (b) (4)	18 Dec 2020 18:43:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:45:12
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'medical history updated' (Site from DM).	Sandra Clancy (b) (4)	20 Jan 2021 23:25:33
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:39:23
DataPoint Verified.	(b) (4)	08 Jan 2021 22:21:27
User entered 'benign prostatic hypertrophy'	Sandra Clancy (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0.4'	Sandra Clancy (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:37:19
User closed query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		25 Jan 2021 18:44:43
Query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:26:32
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:26:08
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:26:08
User opened query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:43:41
Query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' canceled (Site from DM).		19 Jan 2021 08:41:38
User opened query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' (Site from DM).		19 Jan 2021 08:39:21
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	20 Jan 2021 23:26:08
User entered '1'	System	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	20 Jan 2021 23:26:08
User entered '1'	System	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	20 Jan 2021 23:26:08
User entered '804 (804)'	System	18 Dec 2020 18:43:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;STREPTOCOCCUS THERMOPHILUS, PRODUCTSYNONYM: RISA-BID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:51:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:51:31
Data point term sent to Coder	System	18 Dec 2020 18:47:11
User entered 'risa-bid probiotic'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'to maintain gut health'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'tablet (TABLET)'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'twice daily (BID)'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '8 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2'	System	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 18:46:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR-RQ: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).		30 Mar 2021 11:29:17
Query 'Per DM CLR-RQ: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'this medication was used during the hospitalization for this subject during which time he was treated for multiple body system failures, resulting in numerous procedures, eventually ending in mechanical ventilation.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:44:10
User opened query 'Per DM CLR-RQ: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:22:55
User closed query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' (Site from DM).		09 Mar 2021 14:09:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:03:42

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:03:42 08 Mar 2021 19:02:29 08 Mar 2021 19:02:02
Query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' answered with 'this med is not part of AE #8; updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:01:49
User opened query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:47:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:37:35
User closed query 'Per DM CLR: This Con Med was added on 4 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:48:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:45:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:45:28
Data point term sent to Coder	System	20 Jan 2021 23:41:04

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: This Con Med was added on 4 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'updated' (Site from DM). Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:41:01
	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:40:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 23:31:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 23:31:09
Data point term sent to Coder	System	20 Jan 2021 23:30:00
User entered 'VERSED' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:29:49
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:29:28
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:29:28
User entered 'VERSED, worsening' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:29:28
User opened query 'Per DM CLR: This Con Med was added on 4 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 07:51:33
		08 Jan 2021 22:21:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 20:58:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 20:58:39
Data point term sent to Coder	System	18 Dec 2020 18:48:12
User entered 'versed'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	15 Mar 2021 16:49:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 19:02:02
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 19:02:02
User entered 'Anxiety' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 19:02:02
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:37:37
DataPoint Un-verified.	Sandra Clancy (b) (4)	20 Jan 2021 23:40:54
	(b) (4)	
User entered 'acute renal failure' reason for change: Data Entry Error	Sandra Clancy (b) (4)	20 Jan 2021 23:40:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'anxiety'	Sandra Clancy (b) (4)	18 Dec 2020 18:47:44
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:47:44

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 21:00:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 21:00:39
Data point term sent to Coder	System	18 Dec 2020 19:09:30
User entered 'xopenex nebulizer'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: For CM Line #s 18 & 20: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:51:07
Query 'Per DM CLR: For CM Line #s 18 & 20: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE is pending signature' (Site from DM).	Sandra Clancy (b) (4)	20 Jan 2021 23:45:07
User opened query 'Per DM CLR: For CM Line #s 18 & 20: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:04:40
DataPoint Verified.	(b) (4)	08 Jan 2021 22:21:27
User entered 'atelectasis, bilateral lower lobes'	Sandra Clancy (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1.25'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:37:59
User closed query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		25 Jan 2021 18:51:25
Query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.'	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:49:57
answered with 'medication was given at 3 different time points on 05Nov.' (Site from DM).		
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:49:16
User entered 'three times daily (TID)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:49:16
User opened query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:04:56
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'four times daily (QID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '3'	System	20 Jan 2021 23:49:16
User entered '4'	System	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:08:36

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:47:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:47:19
Data point term sent to Coder	System	27 Jan 2021 18:10:16
Coding entries removed.	Sandra Clancy (b) (4)	27 Jan 2021 18:09:43
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:26:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:26:02
Data point term sent to Coder	System	18 Dec 2020 18:56:17
User entered 'morphine sulfate'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:38:12
DataPoint Un-verified.	Sandra Clancy (b) (4)	27 Jan 2021 18:09:43
User entered 'obstructing nephrolithiasis' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	27 Jan 2021 18:09:43
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'intractable renal colic'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '2'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 18:56:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:21:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:21:40
Data point term sent to Coder	System	18 Dec 2020 19:10:30
User entered 'atrovert nebulizer'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'atelectasis, bilateral lower lobes'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0.5'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:38:30
User closed query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		29 Jan 2021 12:59:03
Query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.'	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:52:21
answered with 'medication was given at 3 different time points o 05Nov.' (Site from DM).		
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:51:59
User entered 'three times daily (TID)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:51:59
User opened query 'Per DM CLR: Frequency = four times daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:22:52
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'four times daily (QID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '3'	System	20 Jan 2021 23:51:59
User entered '4'	System	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:10:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
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)	28 Jan 2021 12:46:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:46:17
Data point term sent to Coder	System	27 Jan 2021 18:11:17
Coding entries removed.	Sandra Clancy (b) (4)	27 Jan 2021 18:11:08
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
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)	18 Dec 2020 19:26:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:26:02
Data point term sent to Coder	System	18 Dec 2020 19:12:32
User entered 'meropenem'	Sandra Clancy (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:38:40
DataPoint Un-verified.	Sandra Clancy (b) (4)	27 Jan 2021 18:11:08
User entered 'klebsiella complicated pyelonephritis'	(b) (4)	
reason for change: Data Entry Error	Sandra Clancy (b) (4)	27 Jan 2021 18:11:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'complicated urinary tract infection'	Sandra Clancy (b) (4)	18 Dec 2020 19:11:37
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '500'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 12:59:58
Query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with '2 doses were given on the one day' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:53:09
User opened query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:33:22
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2'	System	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:11:37

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:38:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM; SENNA ALEXANDRINA, PRODUCTSYNONYM: SENOKOT-S - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:02:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:02:11
Data point term sent to Coder	System	25 Jan 2021 23:02:30
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 23:01:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:44:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:44:16
Data point term sent to Coder	System	20 Jan 2021 23:57:23
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:57:18
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:57:18
User entered 'SENOKOT (senna/docusate sodium 8.6/50 mg)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:57:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 23:56:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 23:56:11
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4)	20 Jan 2021 23:55:21 20 Jan 2021 23:54:27
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:13:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:13:40
Data point term sent to Coder User entered 'senokot'	System Sandra Clancy (b) (4)	18 Dec 2020 19:12:33 18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:40:47
User closed query 'Per DM CLR: Re query: Response noted however no updates are found in MH or AE. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Thank you.' (Site from DM).		01 Feb 2021 08:32:27
Query 'Per DM CLR: Re query: Response noted however no updates are found in MH or AE. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Thank you.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 23:02:02
User entered 'obstructing nephrolithiasis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 23:01:46
User opened query 'Per DM CLR: Re query: Response noted however no updates are found in MH or AE. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:22:22
User closed query 'Per DM CLR: For CM Line #s 22 & 26: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		25 Jan 2021 19:22:22
Query 'Per DM CLR: For CM Line #s 22 & 26: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:54:37
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:54:27
User entered 'CONSTIPATION due to the opioids used to control pain' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:54:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: For CM Line #s 22 & 26: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 09:06:11
	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'constipation'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:39:49
User closed query 'Per DM CLR: Response noted. However dose and dose unit are not updated. Kindly update Dose and dose unit as appropriate. Thank you.' (Site from DM).		25 Jan 2021 19:19:47
Query 'Per DM CLR: Response noted. However dose and dose unit are not updated. Kindly update Dose and dose unit as appropriate. Thank you.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:08:10
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:07:59
User entered '17.2/100' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:07:59
User opened query 'Per DM CLR: Response noted. However dose and dose unit are not updated. Kindly update Dose and dose unit as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:02:15
User closed query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		25 Jan 2021 19:02:15
Query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Jan 2021 23:57:26
User opened query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:06:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '2'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:40:14
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Jan 2021 19:07:59
User entered 'mg (mg)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:07:59
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'tablet (TABLET)'	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:12:27

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 09:23:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 09:23:05
Data point term sent to Coder	System	25 Jan 2021 19:10:37
Coding entries removed.	Sandra Clancy (b) (4)	25 Jan 2021 19:10:11
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:14:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:14:41
Data point term sent to Coder	System	18 Dec 2020 19:13:34
User entered 'melatonin'	Sandra Clancy (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:40:31
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		29 Jan 2021 09:36:32
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:10:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:10:11
User entered 'INSOMNIA following laparotomy for obstructing nephrolithiasis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:10:11
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:07:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'insomnia'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '3'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '4 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:13:31

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:05:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:05:50
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:04:31 08 Mar 2021 19:04:11
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:03:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:03:40
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:02:26 21 Jan 2021 00:01:34
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:17:02

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Dec 2020 19:17:02
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	18 Dec 2020 19:15:35
User entered 'hydrocodone/APAP'	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please note, there is a medical condition PERFORATED DUODENAL ULCER Start/End date=08 NOV 2020. Please confirm if this Con Med is given for this medical condition. Review and update Indication if applicable and ensure to reconcile dates with AE entries so there is an appropriate match. Otherwise, provide clarification ' (Site from DM).		30 Mar 2021 11:29:57
Query 'Per DM CLR: Please note, there is a medical condition PERFORATED DUODENAL ULCER Start/End date=08 NOV 2020. Please confirm if this Con Med is given for this medical condition. Review and update Indication if applicable and ensure to reconcile dates with AE entries so there is an appropriate match. Otherwise, provide clarification ' answered with 'entry is correct - the actual date of identification of the pain--which was the perforated duodenal ulcer--occurred during the exploratory laparotomy on 8nov2020. They did not know the source of the pain until subject was in OR.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:47:22
User opened query 'Per DM CLR: Please note, there is a medical condition PERFORATED DUODENAL ULCER Start/End date=08 NOV 2020. Please confirm if this Con Med is given for this medical condition. Review and update Indication if applicable and ensure to reconcile dates with AE entries so there is an appropriate match. Otherwise, provide clarification ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:46:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:49:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 19:04:11
Signature has been broken.	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 19:04:11

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain associated with PERFORATED DUODENAL ULCER' reason for change: Data Entry Error	Sandra Clancy (b) (4)	08 Mar 2021 19:04:11
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:40:42
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:01:34
User entered 'perforated duodenal ulcer' reason for change: Data Entry Error	Sandra Clancy (b) (4)	21 Jan 2021 00:01:34
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'intractable renal colic'	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10/325'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'PER DM CLR: RE-QUERY: Per response updated. However, still Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 18:35:51
Query 'PER DM CLR: RE-QUERY: Per response updated. However, still Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate. Thank you.' answered with 'this med has nothing to do with AE on 08Nov. entry is correct as is' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	09 Mar 2021 18:26:46
User opened query 'PER DM CLR: RE-QUERY: Per response updated. However, still Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:05:00
User closed query 'Per DM CLR: Please note that Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate.	(b) (4), (b) (6)	09 Mar 2021 14:03:10
' (Site from DM).		
Query 'Per DM CLR: Please note that Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:04:19
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Please note that Con Med start date (5 NOV 2020) is prior to the start date of the corresponding AE (8 NOV 2020). Please review and reconcile the Con Med and AE start dates and correct as appropriate.	(b) (4), (b) (6)	08 Mar 2021 01:41:09
' (Site from DM).		
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '5 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:15:06

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:12:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:12:52
Data point term sent to Coder	System	18 Dec 2020 19:17:36
User entered 'protonix'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'GI protection'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '40'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '7 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '9 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:17:18

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:07:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:07:49
Data point term sent to Coder	System	08 Mar 2021 19:06:32
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:05:48
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:19:45
Data point term sent to Coder	System	18 Dec 2020 19:18:36
User entered 'miralax'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	15 Mar 2021 16:48:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
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)	09 Mar 2021 14:07:10
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' (Site from DM).	Sandra Clancy (b) (4)	08 Mar 2021 19:06:01
DataPoint Un-verified.	(b) (4)	08 Mar 2021 19:05:48
Signature has been broken.	Sandra Clancy (b) (4)	08 Mar 2021 19:05:48
User entered 'crohn's disease' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 19:05:48
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).	Sandra Clancy (b) (4)	08 Mar 2021 01:43:09
User signature succeeded.	(b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'constipation'	Sandra Clancy (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '17'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'g (g)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:41:07
User closed query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		29 Jan 2021 13:00:45
Query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:02:24
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:02:09
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:02:09
User opened query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:34:10
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
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 CROHN'S DISEASE should be recorded, and update con med indication or provide clarification. ' (Site from DM).		30 Mar 2021 11:30:31
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 CROHN'S DISEASE should be recorded, and update con med indication or provide clarification. ' answered with 'there is no indication that Crohn's worsened; this medication was used during the hospitalization.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:49:44
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 CROHN'S DISEASE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:49:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '6 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '6 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:02:09
User entered '1'	System	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:02:09
User entered '1'	System	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:02:09
User entered '804 (804)'	System	18 Dec 2020 19:18:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
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)	18 Dec 2020 19:26:02
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 19:26:02
Data point term sent to Coder	System	18 Dec 2020 19:20:37
User entered 'lovenox'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'clot prevention'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '30'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:41:47
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4)	01 Feb 2021 07:25:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:04:38
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:04:29
User entered 'mg (mg)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:04:29
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:25:48
DataPoint Verified.	(b) (4)	08 Jan 2021 22:21:27
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '9 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:19:43

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' (Site from DM).		09 Mar 2021 13:54:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN, PRODUCTSYNONYM: ALBUMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:16:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:16:50
Data point term sent to Coder	System	08 Mar 2021 19:21:04
Query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:20:35
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:20:27
User opened query 'Per DM CLR : Please review "Other Action Taken" field for AE #8 in AE eCRF as it does not reflect this Con Med. Please reconcile and correct response as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:33:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:38:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:38:16
Data point term sent to Coder	System	21 Jan 2021 00:10:30
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:09:30
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:24:45
Data point term sent to Coder	System	18 Dec 2020 19:21:40
User entered 'albumin'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Else, clarify. ' (Site from DM).		30 Mar 2021 12:35:26
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Else, clarify. ' answered with 'cirrhosis was a medical history condition that was not provided by the subject - site did not have this information until the hospitalization, which indicates onset to be prior to study entry.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:52:09
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:54:33
DataPoint Verified.		15 Mar 2021 16:48:00
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:20:27
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:20:27
User entered 'protein replacement due to cirrhosis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 19:20:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:42:00

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:28:31
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	21 Jan 2021 00:09:38
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:09:30
User entered 'acute renal failure' reason for change:	Sandra Clancy (b) (4)	21 Jan 2021 00:09:30
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:08:08
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'to increase blood plasma'	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:42:04
User closed query 'Per DM CLR: Please provide the actual dose for this medication in Grams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		25 Jan 2021 19:28:28
Query 'Per DM CLR: Please provide the actual dose for this medication in Grams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:09:44
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:06:58
User entered '25' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:06:58
User opened query 'Per DM CLR: Please provide the actual dose for this medication in Grams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:08:28
DataPoint Verified.		08 Jan 2021 22:21:27
User entered '100'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:42:06
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:06:58
User entered 'g (g)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	21 Jan 2021 00:06:58
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'three times daily (TID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '9 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '3'	System	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:20:56

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:45:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:45:57
Data point term sent to Coder	System	08 Mar 2021 21:13:18
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:12:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 15:21:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 15:21:16
Data point term sent to Coder	System	30 Dec 2020 15:09:16
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:09:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 20:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 20:20:46
Data point term sent to Coder	System	23 Dec 2020 19:37:24
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:37:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:24:45
Data point term sent to Coder	System	18 Dec 2020 19:22:41
User entered 'fluconazole'	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	15 Mar 2021 16:46:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		15 Mar 2021 15:48:01
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 if appropriate.' (Site from DM).		11 Mar 2021 18:36:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
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 if appropriate.' answered with 'correct - it is part of post op care following second surgery.' (Site from DM).	(b) (4)	
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 if appropriate.' (Site from DM).	Sandra Clancy (b) (4)	09 Mar 2021 18:27:43
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 if appropriate.' (Site from DM).	(b) (4)	
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 if appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:26:34
DataPoint Un-verified.		09 Mar 2021 14:26:34
Signature has been broken.	Sandra Clancy (b) (4)	08 Mar 2021 21:12:51
User entered 'post op infection prophylaxis' reason for change: New Information	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:12:39
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Hutchens (b) (4)	24 Feb 2021 03:28:26 19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'candida albicans dubliniensis' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	30 Dec 2020 15:09:05
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:37:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:37:08
User entered 'peritonitis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 19:37:08
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:22:03
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:46:50
User closed query ' Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		25 Jan 2021 19:29:30
Query ' Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. '	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:11:58
answered with 'corrected' (Site from DM).		
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:11:07
User entered '100' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:11:07
User opened query ' Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:13:05
DataPoint Verified.		08 Jan 2021 22:21:27
User entered '50'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:46:54
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:11:07
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	21 Jan 2021 00:11:07
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:46:56
User closed query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		25 Jan 2021 19:29:33
Query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:12:03
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:11:43
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:11:43
User opened query 'Per DM CLR: Frequency = once daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:13:45
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:11:43
User entered '1'	System	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:11:43
User entered '1'	System	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:11:43
User entered '804 (804)'	System	18 Dec 2020 19:22:03

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: SOLUTIONS FOR PARENTERAL NUTRITION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:31:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:31:51
Data point term sent to Coder	System	15 Mar 2021 18:11:15
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:10:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: SOLUTIONS FOR PARENTERAL NUTRITION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:29:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:29:41
Data point term sent to Coder	System	18 Dec 2020 19:24:42
User entered 'adult TPN formula'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:48:50
DataPoint Un-verified.	Sandra Clancy (b) (4)	15 Mar 2021 18:09:44
Signature has been broken.	(b) (4) Sandra Clancy (b) (4)	15 Mar 2021 18:09:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	15 Mar 2021 18:09:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:48:53
DataPoint Un-verified.	Sandra Clancy (b) (4)	15 Mar 2021 18:10:57
Signature has been broken.	(b) (4) Sandra Clancy (b) (4)	15 Mar 2021 18:10:57
User entered 'prophylaxis for malnutrition' reason for change: Data Entry Error	Sandra Clancy (b) (4)	15 Mar 2021 18:10:57
User signature succeeded.	(b) (4) Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:34:22
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE pending signature' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:14:11
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:15:53
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'malnutrition'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '720'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:12:19
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' answered with 'indication updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:10:12
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 04:48:44
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '12 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2'	System	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:23:45

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 23:08:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:08:03
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 23:07:38 25 Jan 2021 23:06:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:40:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:40:21
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:19:34 21 Jan 2021 00:19:32
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:26:02

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Dec 2020 19:26:02
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	18 Dec 2020 19:24:42
User entered 'lopressor'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Re query: Response noted. Please split the indication and update separately as appropriate on AE page. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:23:08
DataPoint Verified.		02 Feb 2021 16:48:13
Query 'Per DM CLR: Re query: Response noted. Please split the indication and update separately as appropriate on AE page. Thank you.' answered with 'this event was transient - like many other events, it was an outcome that cascaded from a larger event.' (Site from DM).	Sandra Clancy (b) (4)	25 Jan 2021 23:08:09
User entered 'hypertension' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:06:58
User opened query 'Per DM CLR: Re query: Response noted. Please split the indication and update separately as appropriate on AE page. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:00:58
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		25 Jan 2021 20:00:58
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'clarified' (Site from DM).	Sandra Clancy (b) (4)	21 Jan 2021 00:19:41
DataPoint Un-verified.	Sandra Clancy (b) (4)	21 Jan 2021 00:19:32
User entered 'HYPERTENSION due to increased pain attributed to perforated duodenal ulcer' reason for change: Data Entry Error	Sandra Clancy (b) (4)	21 Jan 2021 00:19:32

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 09:16:53
	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'hypertension'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '25'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '12 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '16 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '2'	System	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	18 Dec 2020 19:24:38

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:20:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:20:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:19:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:19:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:56:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:56:31
Data point term sent to Coder	System	08 Mar 2021 21:17:20
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:17:08
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:01:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:01:27
Data point term sent to Coder	System	25 Jan 2021 19:12:41
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 19:12:02
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:32:21
Data point term sent to Coder	System	18 Dec 2020 19:52:11
Data point term sent to Coder	System	18 Dec 2020 19:27:53
User entered 'potassium chloride'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).		30 Mar 2021 11:30:55
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'corrected per query' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	29 Mar 2021 23:56:13
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:56:21
DataPoint Verified.		15 Mar 2021 15:45:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:51:56
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:07:51
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:17:17
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:17:08
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:17:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERNATREMIA /low potassium, ongoing acUTE RENAL FAILURE' reason for change: Data Entry Error	Sandra Clancy (b) (4)	08 Mar 2021 21:17:08
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:45:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:48:24
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		29 Jan 2021 09:37:07
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	25 Jan 2021 19:12:09
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Jan 2021 19:12:02
User entered 'HYPERNATREMIA while managing acute renal failure' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Jan 2021 19:12:02
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:17:37
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'hypernatremia' reason for change: Data Entry Error	Sandra Clancy (b) (4)	18 Dec 2020 19:51:18
User entered 'corrective supplement'	Sandra Clancy (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'meq'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Dec 2020 19:27:48
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	18 Dec 2020 19:27:48
User entered 'as needed (PRN)' reason for change:	Sandra Clancy (b) (4)	18 Dec 2020 19:27:48
Data Entry Error	(b) (4)	
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Dec 2020 19:27:08
User entered 'once (ONCE)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '15 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:27:08

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM PHOSPHATE DIBASIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:42:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:42:51
Data point term sent to Coder	System	18 Dec 2020 19:29:54
User entered 'potassium phosphate'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:01:49
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'correct as is' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:34:41
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:12:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'corrective supplement'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mm'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once (ONCE)'	Sandra Clancy (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '16 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '16 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:29:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Jan 2021 07:43:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:43:17
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4)	21 Jan 2021 00:38:38 21 Jan 2021 00:37:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:37:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:37:42
Data point term sent to Coder User entered 'lasix'	System Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:54 18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:48:44
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	(b) (4)	29 Jan 2021 09:37:23
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:37:59
User entered 'FLUID OVERLOAD due to acute renal failure' reason for change: Data Entry Error	Sandra Clancy (b) (4)	21 Jan 2021 00:37:52
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:18:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'fluid overload'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '80'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'once (ONCE)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '18 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '18 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4)	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:30:26

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:36:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:36:41
Data point term sent to Coder	System	18 Dec 2020 19:35:58
User entered 'diprivan'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:35:53
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:35:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'sedation for mechanical ventilation'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '10'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '21 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	18 Dec 2020 19:35:40

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:45:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: MUPIROCIN, PRODUCTSYNONYM: BACTROBAN [MUPIROCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:42:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 19:42:51
Data point term sent to Coder	System	18 Dec 2020 19:37:59
User entered 'bactroban'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:45:08
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per DM CLR: Re query: No medical condition found in MH or AE page matching to this indication. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:11:31
Query 'Per DM CLR: Re query: No medical condition found in MH or AE page matching to this indication. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'transient event - subject was intubated' (Site from DM).	Sandra Clancy (b) (4)	25 Jan 2021 23:17:11
User opened query 'Per DM CLR: Re query: No medical condition found in MH or AE page matching to this indication. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:13:41
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:13:41
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'indication is correct' (Site from DM).	Sandra Clancy (b) (4)	21 Jan 2021 00:35:58
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:33:42
DataPoint Verified.		08 Jan 2021 21:45:10

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
User entered 'restore moisture'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '1'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'application'	Sandra Clancy (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:49:34
User closed query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		25 Jan 2021 20:07:47
Query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:36:14
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:36:07
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 00:36:07
User opened query 'Per DM CLR: Frequency = twice daily, however Con Med was given for 1 day duration only. Please verify and update either the frequency (e.g., once) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:33:29
DataPoint Verified.		08 Jan 2021 22:21:27
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'Nasal (NASAL)'	Sandra Clancy (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '0'	Sandra Clancy (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:21:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:36:07
User entered '2'	System	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:36:07
User entered '1'	System	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	21 Jan 2021 00:36:07
User entered '804 (804)'	System	18 Dec 2020 19:37:01

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE BITARTRATE, PRODUCTSYNONYM: LEVOPHED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 15:53:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:53:26
Data point term sent to Coder	System	03 Feb 2021 15:52:46
User entered 'Levophed'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Currently unknown'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '8'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'mg (mg)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'once (ONCE)'	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '21 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '0'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '21 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:52:09
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:52:09

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 11:51:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 11:51:45
Data point term sent to Coder	System	03 Feb 2021 15:53:46
User entered 'Sodium bicarbonate'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Currently unknown'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '650'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:53:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'mg (mg)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'three times daily (TID)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:53:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Oral (ORAL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:53:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '06 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '10 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '3'	System	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	03 Feb 2021 15:53:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE, PRODUCTSYNONYM: CITRATE OF MAGNESIA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 12:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:19:55
Data point term sent to Coder	System	03 Feb 2021 15:54:47
User entered 'Citrate of magnesia'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Currently unknown'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '300'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'mL (mL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'once (ONCE)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:54:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:54:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Oral (ORAL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:54:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '07 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '07 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:54:16
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered empty.	System	03 Feb 2021 15:54:16

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC SODIUM GLUCONATE COMPLEX, PRODUCTSYNONYM: NULECIT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:37:35
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 Mar 2021 10:37:35
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 21:18:15 17 Mar 2021 21:18:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC SODIUM GLUCONATE COMPLEX, PRODUCTSYNONYM: NULECIT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:30:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:30:43
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:30:53 08 Mar 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC SODIUM GLUCONATE COMPLEX, PRODUCTSYNONYM: NULECIT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:53:47

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Nulecit'	Coder Import (b) (4) (b) (4) System Mia Rountree (b) (4) (b) (4)	15 Feb 2021 21:53:47 03 Feb 2021 15:55:47 03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4)	30 Mar 2021 18:15:53
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'corrected per query' (Site from DM).	Sandra Clancy (b) (4)	30 Mar 2021 00:02:53
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 08:30:50
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:37
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:49:23
User closed query 'Iron Deficiency is not listed in source documentation as Med Hx or Adverse Event. Please clarify, or consider adding to Adverse Event/Med Hx.' (Site from CRA).	(b) (4)	17 Mar 2021 21:43:44
Query 'Iron Deficiency is not listed in source documentation as Med Hx or Adverse Event. Please clarify, or consider adding to Adverse Event/Med Hx.' answered with 'updated' (Site from CRA).	Sandra Clancy (b) (4)	17 Mar 2021 21:18:21
DataPoint Un-verified.	Sandra Clancy (b) (4)	17 Mar 2021 21:18:12
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 21:18:12
User entered 'anemia' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 21:18:12
User opened query 'Iron Deficiency is not listed in source documentation as Med Hx or Adverse Event. Please clarify, or consider adding to Adverse Event/Med Hx.' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 15:44:21

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 15:42:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:30:18
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	08 Mar 2021 21:30:18
User entered 'iron deficiency' reason for change:	(b) (4)	
Data Entry Error	Sandra Clancy (b) (4)	08 Mar 2021 21:30:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
	(b) (4)	
User entered 'Currently unknown'	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		15 Mar 2021 15:44:53
User closed query 'Per DM CLR: RE-QUERY: Response noted. However, please consider reviewing the dose unit and update as appropriate. Thank you.' (Site from DM).		11 Mar 2021 18:35:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
Query 'Per DM CLR: RE-QUERY: Response noted. However, please consider reviewing the dose unit and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4) Sandra Clancy (b) (4)	09 Mar 2021 18:29:17
User entered '10' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: RE-QUERY: Response noted. However, please consider reviewing the dose unit and update as appropriate. Thank you.' (Site from DM).	Sandra Clancy (b) (4) (b) (4), (b) (6)	09 Mar 2021 18:29:11 09 Mar 2021 13:50:19
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		09 Mar 2021 13:50:19
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:30:26
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:30:18
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:30:18
User entered '12.5' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:30:18
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 09:46:06
DataPoint Verified.		03 Mar 2021 16:00:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
	(b) (4)	
User entered '125'	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'mL (mL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Mia Rountree (b) (4)	10 Feb 2021 16:55:34
User entered 'other (OTHER)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Per CDM: Frequency was recorded as 'Other' and If frequency is Other, specify was recorded as 'EVERY 24 HOURS'. However, instead of entering Other- EVERY 24 HOURS, if appropriate please consider selecting 'Once Daily' from available options in Frequency field. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 12:06:20
Query 'Per CDM: Frequency was recorded as 'Other' and If frequency is Other, specify was recorded as 'EVERY 24 HOURS'. However, instead of entering Other- EVERY 24 HOURS, if appropriate please consider selecting 'Once Daily' from available options in Frequency field. Thank you. ' answered with 'Data corrected' (Site from DM).	Mia Rountree (b) (4) (b) (4)	10 Feb 2021 16:55:47
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	10 Feb 2021 16:55:34
User opened query 'Per CDM: Frequency was recorded as 'Other' and If frequency is Other, specify was recorded as 'EVERY 24 HOURS'. However, instead of entering Other- EVERY 24 HOURS, if appropriate please consider selecting 'Once Daily' from available options in Frequency field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:33:01
User entered 'Every 24 hours'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (ANEMIA Start date=15NOV2020). Please review and reconcile Con Med and AE start dates as appropriate. ' (Site from DM).		30 Mar 2021 18:17:56
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (ANEMIA Start date=15NOV2020). Please review and reconcile Con Med and AE start dates as appropriate. ' answered with 'entry is correct per medical records; while the event has a specific 'start date', the subject's medical condition was present prior to being identified and medical care was warranted.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 00:18:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (ANEMIA Start date=15NOV2020). Please review and reconcile Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 08:29:26
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile Con Med and eDiary start dates as appropriate. ' canceled (Site from DM).		28 Mar 2021 08:21:46
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile Con Med and eDiary start dates as appropriate. ' (Site from DM).		28 Mar 2021 08:19:44
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '12 Nov 2020'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 15:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:55:56
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	03 Feb 2021 15:55:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 15:55:41
User entered empty.	System	03 Feb 2021 15:55:41
	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 15:55:56
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 16:00:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	03 Feb 2021 15:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:55:56
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	03 Feb 2021 15:55:56
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:55:41
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 15:55:41
	(b) (4)	

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	10 Feb 2021 16:55:34
User entered empty.	System	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '1'	System	10 Feb 2021 16:55:34
User entered empty.	System	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '804 (804)'	System	10 Feb 2021 16:55:34
User entered empty.	System	03 Feb 2021 15:55:41

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:19:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:33
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:41:55

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:57:00
User entered '21 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:42:26

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:00
User entered 'Intubation'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:42:26

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:00
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:42:26

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:00
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:42:26

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:56
User entered '15 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:44:16

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:56
User entered 'Packed red blood cells'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:44:16

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:56
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:44:16

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:44:16

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:56:52
User entered '21 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:45:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:52
User entered 'Packed red blood cells'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:45:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:52
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:45:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:52
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:45:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User closed query 'Please provide source for concomitant procedure.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:14:36
Query 'Please provide source for concomitant procedure.' answered with 'explain please what is needed here' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 21:31:37
User opened query 'Please provide source for concomitant procedure.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 15:49:41
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:48:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:01:23
Query 'Please provide source to CRA for review. ' canceled (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 20:30:48
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:31
User opened query 'Please provide source to CRA for review. ' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:14
User entered '8 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:45:50

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 15:48:18
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:33
DataPoint Verified.	(b) (4)	09 Dec 2020 17:50:15
User entered 'platelet transfusion'	Tina Rountree (b) (4)	29 Nov 2020 18:45:50
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 15:48:18
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:34
DataPoint Verified.	(b) (4)	09 Dec 2020 17:50:17
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4)	29 Nov 2020 18:45:50
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	03 Mar 2021 15:48:18
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 17:50:35
DataPoint Verified.	(b) (4)	09 Dec 2020 17:50:18
User entered empty.	Tina Rountree (b) (4)	29 Nov 2020 18:45:50
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:47:41
User entered '17 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:46:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:47:41
User entered 'platelet transfusion'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:46:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:47:41
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4)	29 Nov 2020 18:46:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:47:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:46:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:32:09
User entered '8 Nov 2020'	Tina Rountree (b) (4)	29 Nov 2020 18:47:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:32:09
User entered 'graham patch'	Tina Rountree (b) (4)	29 Nov 2020 18:47:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:32:09
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:47:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:32:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:47:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:12:35
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:48:38

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:12:35
User entered 'ureteral stent'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:48:38

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:12:35
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:48:38

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:12:35
User entered empty.	Tina Rountree (b) (4) (b) (4)	29 Nov 2020 18:48:38

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:25:53
User entered '8 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 21:49:30
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	18 Dec 2020 21:47:38
DataPoint inactivated with code reason code Data not required.	Tina Rountree (b) (4)	29 Nov 2020 18:51:23

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:25:53
User entered 'drain placement posterior superior to the perforated duodenal ulcer'	Sandra Clancy (b) (4)	18 Dec 2020 21:49:30
DataPoint activated with code reason code Data required.	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:47:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Tina Rountree (b) (4)	29 Nov 2020 18:51:23

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:25:53
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	18 Dec 2020 21:49:30
DataPoint activated with code reason code Data required.	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:47:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Tina Rountree (b) (4)	29 Nov 2020 18:51:23

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:19:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:25:53
User entered empty.	Sandra Clancy (b) (4)	18 Dec 2020 21:49:30
DataPoint activated with code reason code Data required.	(b) (4) Sandra Clancy (b) (4)	18 Dec 2020 21:47:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Tina Rountree (b) (4)	29 Nov 2020 18:51:23

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:25:50
User entered '8 Nov 2020'	Sandra Clancy (b) (4)	18 Dec 2020 21:54:57

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:25:50
User entered 'lysis of adhesions from abdominal wall'	Sandra Clancy (b) (4)	18 Dec 2020 21:54:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:25:50
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:54:57

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:25:50
User entered empty.	Sandra Clancy (b) (4) (b) (4)	18 Dec 2020 21:54:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:51
User entered '4 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 16:49:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:51
User entered 'cystourethroscopy with left retrograde ureteropyelogram'	Sandra Clancy (b) (4)	21 Jan 2021 16:49:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:51
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:49:21

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:51
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 16:49:21

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:58:50
User entered '3 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:42:47

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:58:53
User entered 'CT of abdomen/pelvis'	Sandra Clancy (b) (4)	21 Jan 2021 16:42:47

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:58:56
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:42:47

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:58:58
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:42:47

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:00:23
User entered '3 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 16:46:15

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:00:26
User entered 'x-ray cystogram'	Sandra Clancy (b) (4)	21 Jan 2021 16:46:15

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:00:28
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:46:15

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:00:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:46:15

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:00:51
User entered '6 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:52:30

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:00:53
User entered 'renal ultrasound'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:52:30

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:00:56
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4)	21 Jan 2021 16:52:30

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:00:59
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:52:30

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:01:35
User entered '8 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 16:58:00

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:01:38
User entered 'CT of abdomen/pelvis without contrast'	Sandra Clancy (b) (4)	21 Jan 2021 16:58:00

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:01:43
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4)	21 Jan 2021 16:58:00

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:01:46
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 16:58:00

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:02:02
User entered '8 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:00:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:02:05
User entered 'exploratory laparotomy with closure of duodenal ulcer'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:00:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:02:09
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	21 Jan 2021 17:00:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:02:11
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:00:05

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:03:03
User entered '11 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:01:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:03:06
User entered 'x-ray upper GI'	Sandra Clancy (b) (4)	21 Jan 2021 17:01:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:03:08
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:01:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:03:10
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:01:13

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:04:36
User entered '13 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:02:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:04:38
User entered 'CT of abdomen/pelvis without contrast'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:02:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:04:41
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:02:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:04:43
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 17:02:03

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:43
User entered '15 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:03:41

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:43
User entered 'x-ray abdomen /kidneys,ureter, bladder'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:03:41

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:43
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:03:41

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:43
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:03:41

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:40
User entered '18 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:05:59

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:40
User entered 'x-ray chest'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:05:59

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:40
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:05:59

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:40
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 17:05:59

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:36
User entered '19 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:08:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:36
User entered 'CT abdomen/pelvis without contrast'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:08:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:36
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:08:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:36
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:08:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:33
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:10:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:33
User entered 'CT guided drain placement'	Sandra Clancy (b) (4)	21 Jan 2021 17:10:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:33
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:12:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 17:12:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:12:40
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:10:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:10:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:33
User entered empty.	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:10:20

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:30
User entered '20 Nov 2020'	Sandra Clancy (b) (4)	21 Jan 2021 17:13:58

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:30
User entered 'x-ray chest'	Sandra Clancy (b) (4)	21 Jan 2021 17:13:58

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:06:30
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 17:13:58

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:06:30
User entered empty.	Sandra Clancy (b) (4)	21 Jan 2021 17:13:58

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:19:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:26:53
User entered '22 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:26:54
User entered 'Death (DEATH)'	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

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)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 22:26:56
User entered empty.	Sandra Clancy (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:26:58
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	10 Dec 2020 20:25:30
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	10 Dec 2020 20:24:10
User entered 'Adverse event (ADVERSE EVENT)'	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:27:11
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	10 Dec 2020 20:25:30
User entered '7'	(b) (4) Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:27:12
User entered '22 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:45

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:27:14
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 20:24:10

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:47:46
User entered '16/Nov/2020 18:39'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:47:46
User entered '1'		16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:39:03
	(b) (4)	16 Nov 2020 23:35:36
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
	(b) (4)	
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:12
User entered '27/Nov/2020 09:43'	System	27 Nov 2020 14:43:54

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:12
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered '1'		27 Nov 2020 14:43:54

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:39:03
	(b) (4)	16 Nov 2020 23:35:36
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:11
User entered '27/Nov/2020 22:39'	System	28 Nov 2020 03:39:15

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:11
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered '1'		28 Nov 2020 03:39:15

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:10
User entered '30/Nov/2020 19:38'	System	30 Nov 2020 19:38:28

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:20:08
DataPoint Verified.		01 Dec 2020 21:11:10
User entered '1'		30 Nov 2020 19:38:28

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	System	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
	(b) (4)	
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:56
User entered '21/Dec/2020 15:20'	System	21 Dec 2020 15:20:39

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:56
Reviewed for Safety.		28 Dec 2020 16:48:45
User entered '1'		21 Dec 2020 15:20:39

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4)	16 Nov 2020 23:39:03
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:55
User entered '22/Dec/2020 11:33'	System	22 Dec 2020 16:33:30

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:55
Reviewed for Safety.		22 Dec 2020 16:33:36
User entered '1'		22 Dec 2020 16:33:30

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:39:03
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:54
User entered '28/Dec/2020 16:48'	System	28 Dec 2020 16:49:15

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:54
Reviewed for Safety.		28 Dec 2020 17:01:27
User entered '1'		28 Dec 2020 16:49:15

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4)	16 Nov 2020 23:39:03
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:52
User entered '28/Dec/2020 17:01'	System	28 Dec 2020 17:02:01

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:52
Reviewed for Safety.		30 Dec 2020 15:39:50
User entered '1'		28 Dec 2020 17:02:01

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:50
User entered '30/Dec/2020 15:40'	System	30 Dec 2020 15:40:28

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:50
Reviewed for Safety.		30 Dec 2020 17:18:36
User entered '1'		30 Dec 2020 15:40:28

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	System	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:30:49
User entered '04/Jan/2021 14:34'	System	04 Jan 2021 14:34:24

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:18:50
DataPoint Verified.		08 Jan 2021 22:30:49
User entered '1'		04 Jan 2021 14:34:24

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:42
User entered '22/Jan/2021 07:18'	System	22 Jan 2021 12:19:20

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:42
Reviewed for Safety.		26 Jan 2021 13:09:52
User entered '1'		22 Jan 2021 12:19:20

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:39
User entered '26/Jan/2021 08:10'	System	26 Jan 2021 13:10:19

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:39
Reviewed for Safety.		26 Jan 2021 15:10:18
User entered '1'		26 Jan 2021 13:10:19

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:36
User entered '29/Jan/2021 15:50'	System	29 Jan 2021 20:50:51

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:36
Reviewed for Safety.		29 Jan 2021 21:13:14
User entered '1'		29 Jan 2021 20:50:51

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	System	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:32
User entered '29/Jan/2021 16:13'	System	29 Jan 2021 21:13:47

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:40:02
DataPoint Verified.		02 Feb 2021 16:18:32
User entered '1'		29 Jan 2021 21:13:47

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	System	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 15:51:29
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '11/Feb/2021 12:39'	(b) (4) System	11 Feb 2021 17:39:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		03 Mar 2021 15:51:29
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:40:02
User entered '1'		11 Feb 2021 17:39:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Serious](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	System	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:51:08
User entered '23/Feb/2021 09:28'	System	23 Feb 2021 14:28:32

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:11
DataPoint Verified.		03 Mar 2021 15:51:08
User entered '1'		23 Feb 2021 14:28:32

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4)	16 Nov 2020 23:39:03
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (17)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:51:07
User entered '24/Feb/2021 10:29'	System	24 Feb 2021 15:29:32

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (17)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:27:11
DataPoint Verified.		03 Mar 2021 15:51:07
User entered '1'		24 Feb 2021 15:29:32

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Un-verified.	(b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4)	16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
	(b) (4)	

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.		24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (18)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		15 Mar 2021 16:50:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
User entered '09/Mar/2021 12:26'	(b) (4) System	09 Mar 2021 18:26:59

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (18)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4)	15 Mar 2021 16:50:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:11
User entered '1'	(b) (4)	09 Mar 2021 18:26:59

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

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Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:39:03
	(b) (4)	16 Nov 2020 23:35:36
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (19)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.		15 Mar 2021 16:50:35
User signature succeeded.	Mark Hutchens (b) (4)	15 Mar 2021 14:04:26
User entered '15/Mar/2021 09:01'	(b) (4) System	15 Mar 2021 13:01:23

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (19)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:50:35
User signature succeeded.	Mark Hutchens (b) (4)	15 Mar 2021 14:04:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 13:01:28
User entered '1'	(b) (4), (b) (6)	15 Mar 2021 13:01:23

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'USA-US211-2020-MRNA-1273-P301000006'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:20
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	27 Nov 2020 14:43:09
User entered 'No (N)'	System	25 Nov 2020 00:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	25 Nov 2020 00:33:26
User entered 'No (N)'	(b) (4)	25 Nov 2020 00:32:45
Un-reviewed for Safety.	System	25 Nov 2020 00:32:45
DataPoint Un-verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 00:32:45
DataPoint Verified.	Tina Rountree (b) (4)	25 Nov 2020 00:32:45
Reviewed for Safety.	(b) (4)	24 Nov 2020 21:48:03
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:39:03
	(b) (4)	16 Nov 2020 23:35:36
	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:11:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
User entered 'Yes (Y)'	System	30 Nov 2020 19:27:39
Un-reviewed for Safety.	System	30 Nov 2020 19:24:56
DataPoint Un-verified.	System	30 Nov 2020 19:24:56
User entered 'No (N)'	System	30 Nov 2020 19:24:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:37:44
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:39:03
User entered 'Yes (Y)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'No (N)'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:49
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Mark'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Timothy'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:51:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:55:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
Reviewed for Safety.		23 Feb 2021 14:27:56
Un-reviewed for Safety.	System	23 Feb 2021 14:25:52
DataPoint Un-verified.	System	23 Feb 2021 14:25:52
Signature has been broken.	System	23 Feb 2021 14:25:52
User entered 'Hutchens'	System	23 Feb 2021 14:25:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:03
Reviewed for Safety.		16 Nov 2020 23:39:03
User entered 'Vachris'	System	16 Nov 2020 23:35:36

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.		23 Feb 2021 14:28:02
Un-reviewed for Safety.		23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:04
Reviewed for Safety.		30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:06
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:07
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 19:38:04
User entered empty.	Tina Rountree (b) (4) (b) (4)	25 Nov 2020 00:32:45

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:28:02
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:27:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:38:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:03
User entered 'US'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User entered '20'	System	30 Mar 2021 15:25:33
User entered '19'	System	15 Mar 2021 13:01:23
User entered '18'	System	09 Mar 2021 18:26:59
User entered '17'	System	24 Feb 2021 15:29:32
Signature has been broken.	System	23 Feb 2021 14:28:32
User entered '16'	System	23 Feb 2021 14:28:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:01:23
User entered '15'	System	11 Feb 2021 17:39:36
User entered '14'	System	29 Jan 2021 21:13:47
User entered '13'	System	29 Jan 2021 20:50:51
User entered '12'	System	26 Jan 2021 13:10:19
User entered '11'	System	22 Jan 2021 12:19:20
User entered '10'	System	04 Jan 2021 14:34:24
User entered '9'	System	30 Dec 2020 15:40:28
User entered '8'	System	28 Dec 2020 17:02:01
User entered '7'	System	28 Dec 2020 16:49:15
User entered '6'	System	22 Dec 2020 16:33:30
User entered '5'	System	21 Dec 2020 15:20:39
User entered '4'	System	30 Nov 2020 19:38:28
User entered '3'	System	28 Nov 2020 03:39:15
User entered '2'	System	27 Nov 2020 14:43:54
User entered '1'	System	16 Nov 2020 23:39:17

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (20)

Generated On: 10 Jun 2021 10:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:48:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:21:47
User entered '30/Mar/2021 08:25'	System	30 Mar 2021 15:25:33

US3912024

Folder: SAE USA-US211-2020-MRNA-1273-P301000006

Form: Safety Report Form (20)

Generated On: 10 Jun 2021 10:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:15:51
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:48:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:21:47
User entered '1'		30 Mar 2021 15:25:33